

DIGITAL USG MONITOR  
PRA-ONE

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MANUAL BOOK

## Regulatory Requirement

This guide is a reference for the PRA-ONE. Make sure that you are using the latest revision of this document. If you need the latest revision, contact your existing distributor.



### NOTES:

#### Important

1. No part of this manual may be reduced, modified, copied or reprinted, in whole or in part, without the written permission of PT. Sinko Prima Alloy.
2. The contents of this guide are subject to change without prior notice and without our legal obligations.
3. Before operating the system, please read and understand this manual. After reading, save this guide in an easily accessible place. If you have any questions or doubts, please contact an authorized PT. Sinko Prima Alloy.
4. Warranty from PT. Sinko Prima Alloy only covers repairs of materials and product parts, but does not cover labor costs or on-site repair services.

**NOTES:****Important Information**

1. The customer has the responsibility to maintain and manage the system after product delivery.
2. The warranty does not cover the following, even during the warranty period:
  - a) Damage or loss due to improper treatment or misuse of the system and probe, eg, dropping probes, liquids or metal on the system.
  - b) Damage or loss caused by natural disasters such as fire, earthquake, flood, lightning, etc.
  - c) Damage or loss caused by failure to meet system-defined requirements, such as inadequate power supply, improper installation, or environmental conditions.
  - d) Damage or loss caused by replacement not approved by PT. Sinko Prima Alloy.
  - e) Damage or loss outside the area where the system was originally sold.
  - f) Damage or loss involving the purchase of the system from a source other than PT. Sinko Prima Alloy or a legitimate agent.
3. Do not make changes or modifications to the software or hardware of the system and probe.
4. During operating the system, if the user has any doubts, difficulties or unclear, please contact an authorized technician of PT. Sinko Prima Alloy. Explain the situation clearly to get an immediate answer. Before the problem is solved, do not operate the system.
5. This system is not recommended for use other than by qualified persons and certified medical personnel.
6. Do not use the device for fetal sex examination, unless it is necessary for medical purposes. Devices may only be sold to qualified medical institutions or doctors. Users should understand and master the device before operating it. Users must be qualified, and in accordance with local laws and regulations, local religions and customs, etc.
7. Systems modified or repaired by technicians other than PT. Sinko Prima Alloy, PT. Sinko Prima Alloy is not responsible for the device system.
8. The purpose of this system is to provide data for clinical diagnosis by doctors. The diagnostic procedure is the responsibility of the doctor. PT. Sinko Prima Alloy is not responsible for the results of the diagnostic procedure.
9. These instructions for use contain warnings about potential hazards that may occur, but the user should always be aware of hazards other than those indicated in this manual. PT. Sinko Prima Alloy shall not be liable for any damage or loss resulting from negligence or neglect of the precautions and operating instructions described in this manual.
10. Negligence due to not following the operating manual, PT. Sinko Prima Alloy is not responsible for the results.
11. Before and after each ultrasound examination, check the surface of the probe, the wires and the probe casing for any abnormality, such as cracking, peeling and deforming. Also check if the lens is firmly attached. An abnormal probe may cause electric shock and injure the patient. If the device is abnormal, the user should stop using the device and immediately contact an authorized PT. Sinko Prima Alloy.
12. If the probe is dropped or scratched by a hard object, stop using the probe immediately and contact an authorized PT. Sinko Prima Alloy to ensure the safety and effectiveness of the probe in good condition before use.
13. If any liquid or metal enters the system, turn off the system and stop using it immediately. Please contact an authorized technician of PT. Sinko Prima Alloy to ensure device safety before reuse.
14. Do not use solvents (such as thinner, benzine, or alcohol) or abrasive cleaners to clean the system (including screen and probes, etc.). Doing so can corrode the system and probe.
15. If the system or probe is out of service, please refer to the operating instructions section 9.4.
16. Important data should be backed up on external memory. PT. Sinko Prima Alloy is not responsible for any loss of data stored in system memory caused by operator error.
17. Place this user manual near the system to ensure operators and managers have access to it at all times.

18. The LCD screen display may have some dark or light dots; this is normal for LCD. This does not mean that the LCD screen is faulty.

**⚠ Warning:** Do not use the device for fetal sex examination, unless necessary. Devices may only be sold to qualified medical institutions or doctors. Users should understand and master the device before operating it. Users must meet the requirements, and must comply with local laws and regulations, local religions and customs, etc.

**⚠ Warning:** The user should read the operating manual carefully before operating the device. Turning on the device means that the user has read the operating manual and received the precautions, warnings and notes in the manual. If the user does not agree and cannot accept the warning, the user can request the device to be returned.

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## CHAPTER 1 INTRODUCTION

This manual contains information necessary for the safe operation of the system.

Read and understand all instructions in this manual before operating the system. Always keep this manual with the device, and periodically review operating procedures and precautions.

### 1.1 System Overview

#### Indications for Use

This device is a versatile ultrasonic imaging instrument for use by qualified doctors to evaluate OB, ABD, GYN, Urology, Pediatric, Organ, Cardiac Vascular, MSK etc.

#### Contradiction

This system is NOT intended for eye contact or use where acoustic rays pass through the eye.

### 1.2 Contact Information

For additional information or assistance, please contact your local distributor or appropriate source as indicated below:

Support Service Tel: (62) 31 7482816, 7482835, 7492882  
Fax: (62) 31 7482865  
E-mail: sinkoprima@gmail.com Website: [www.indo-elitech.com](http://www.indo-elitech.com)

Manufacturer PT. Sinko Prima Alloy  
Tambak Osowilangon Permai  
Blok E8 Jalan Osowilangon No.61  
Surabaya 60191 - Indonesia

## CHAPTER 2 SYSTEM SAFETY

### 2.1 Safety Overview

This section discusses measures to ensure operator and patient safety. To ensure the safety of both operator and patient, please read the related details in this chapter carefully before operating the system. Ignoring warnings or violating the relevant rules may result in injury or even loss of life to the operator or patient.

#### Users should observe the following precautions:

- The system complies with Type BF general equipment, and IEC standards.
- Do not modify the system in any way. Necessary modifications should only be made by the manufacturer or its designated agent.
- This system is fully preset at the factory. Do not adjust every part that is already set.
- In case of malfunction, shut down the system immediately and inform the manufacturer or designated agent.
- The power supply cable of the system should only be connected to a grounded electrical socket. Do not disconnect the ground wire for any reason.
- Only connect this system, either electronically or mechanically, to devices that comply with the EN60601-1 standard. Recheck the leakage current and other safety checks on the entire system to avoid potential system damage caused by leakage from superposition currents.
- The system does not include special protective measures in case of operation of the device at high frequencies. Operators should exercise caution when using the device under these conditions.
- The system should only be installed by the manufacturer's designated authority. Do not attempt to install the system yourself.
- Only authorized technicians are allowed to perform maintenance.
- Only a qualified operator, or someone under supervision, can use the system.
- Do not use this system in the presence of flammable substances as explosion may occur.
- Do not continuously scan the same part of the patient or scan the patient for a long time; it can harm the patient.
- When using the system for ultrasound testing, use a quality ultrasound gel that complies with standards.
- Do not unplug the probe while the system is operating. Enter on the EXAM screen display remove the probe.
- To prevent arm or neck injury, the operator is advised not to remain in the same position for too long during a patient scan without resting.
- Do not put liquid on the device.



#### NOTES

\* The system has a built-in screen saver to avoid tic marks on the screen. It is not recommended to turn the unit on and off continuously.

\* To properly dispose of this product, contact your local distributor.

## 2.2 Electrical Safety

### Type of protection against electric shock

- Equipment Class II

CLASS II EQUIPMENT where the tool has been designed so that there is no possibility of the user being electrocuted within reasonable usage limits. The device casing is made of plastic and there are no gaps that would cause the conductor to come into contact with human limbs. protection against electric shock is not



**NOTES:** The power source must be disconnected after disconnecting the power cable and adapter.

### Degree of protection against electric shock

- **BF Type for Connected Parts** (for Probes marked with symbol BF)

TYPE BF FOR CONNECTED PARTS provides a specific level of protection against electric shock, particularly with regard to allowable LEAKAGE CURRENT.

### Level of protection against harmful ingress of water

- Parts of the probe that may come into contact with the operator or patient meet the requirements for drip resistant equipment (IPX1)
- Parts of the probe intended to be immersed in normal use meet the requirements for waterproofing equipment (IPX7)
- IP Classification of the System is Common Equipment (IPX0)

### Safety level in the presence of FLAMMABLE ANESTHETIC MIXED WITH AIR (or OXYGEN or NITROUS OXIDE):

This device is not suitable for use in environments with flammable anesthetics mixed with air (or oxygen or nitrous oxide).

### Mode of operation

- Continuous Operation

For maximum security, always follow these guidelines:

- Proper grounding of the system is essential to avoid electric shock. For protection, ground the frame with a three-wire cord and plug, and plug the system into a standard hospital outlet with three holes.
- Do not disconnect the grounding wire.
- Do not remove the protective cover on the system. This enclosure protects the user from harmful voltages. Cabinet panels must remain in place while the system is in use. A qualified electronics technician may perform internal replacements.
- Do not operate this system in the presence of flammable gases or anesthetics.
- All peripheral devices (unless certified medically fit) connected to the system must be powered via an electrical outlet via an optional isolation transformer.

### Notice Upon Product Installation

The separation distance and effects of fixed radio communication equipment: the field strength of fixed transmitters, such as base stations for radio (cellular/wireless) telephone and mobile radio, amateur radio, AM and FM radio broadcasts, and TV broadcast transmitters cannot be predicted theoretically with accuracy. To assess electromagnetic induced fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the ultrasound system is used exceeds the applicable RF level as stated in the immunity declaration, the ultrasound system must be monitored to verify normal operation. If abnormal operation is observed, additional steps may be required, such as repositioning the ultrasound system or using an RF shielded testing room.

- Use the power cord provided by or designated by PT. Sinko Prima Alloy. Products equipped with a power supply plug must be plugged into a fixed electrical outlet that has a grounding conductor. Do not use an adapter or converter to plug into a power source (eg a three-to-two-prong converter).
- Place the equipment as far away from other electronic equipment as possible.
- Be sure to only use cables supplied by or designated by PT. Sinko Prima Alloy. Connect this cable according to the installation procedure (eg connect the power cable and signal cable separately).
- Remove the main unit and other peripherals according to the installation procedure described in this manual.

### Notice Against User Modification

Users are never allowed to modify this product.

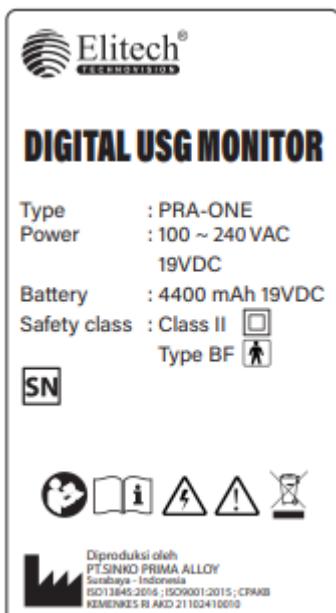
Modifications by users may result in a decrease in Electrical Safety. Product modifications include changes to:

- Cables (length, material, wiring, etc.)
- System/component configuration

Modifications by users may cause a decrease in EMC performance. Product modifications include changes to:

- Cables (length, material, wiring, etc.)
- System installation / layout
- System/component configuration
- Security of system parts (cover open/closed, cover screw)

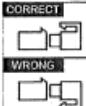
## 2.3 Label



Rear Panel Label

## Warning Symbol

 Caution, see accompanying docs. This symbol advises the reader to see accompanying documents for important safety related information such as warnings and precautions that are not displayed on the tool.	 Electric voltage hazard. Unplug the main plug before opening the system.
 Do not use the following equipment near the device: cellular phones, radio receivers and mobile radio transmitters, radio controlled equipment, etc. Use of such equipment in close proximity to this device may cause the appliance to operate outside of the specifications described. Turn off the equipment when near this device.	 Be careful of static
 WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE) This symbol is used for Environmental Protection, it indicates that waste electrical and electronic equipment should not be disposed of as unsorted waste and must be collected separately. Please contact your local Authority or manufacturer's distributor for information on deactivating your equipment.	 Type-BF for applied part
 This symbol is followed by the serial number of the	 MANUFACTURER: This symbol is

device.	followed by the name and address of the manufacturer
 On/Off button <b>WARNING:</b> The power button cannot completely isolate the main power source	 This symbol indicates that the user manual must be read.
 The “Alternating current” symbol indicates that the equipment is suitable for alternating current only.	 <b>CORRECT:</b> Correct connection of the battery connector <b>WRONG:</b> Incorrect connection of battery connector
 YYYY-MM This symbol is followed by the tool assembly date in YYYY-MM format.	 <b>—</b> Direct current To show that the equipment suitable for direct current only; to identify the appropriate terminal
 Class II equipment for protection against electric shock.	

## 2.4 Patient Environmental Devices

### Left side:

- ◆ 1 LAN port
- ◆ 1 VGA port: external monitor
- ◆ 2 USB ports
- ◆ 1 port footswitch
- ◆ 1 power port

### Rear panel:

- ◆ 2 probe ports
- ◆ 1 USB port
- ◆ 1 video output port
- ◆ 1 remote port

### Acceptable Devices

The Patient Environment Devices shown above are determined to be suitable for use in the PATIENT ENVIRONMENT.



**CAUTION:**

- DO NOT connect probes or accessories without the approval of PT. Sinko Prima Alloy in the PATIENT ENVIRONMENT

- DO NOT touch patients and devices without IEC/EN 60601-1 approval to avoid risk leakage current in the PATIENT ENVIRONMENT.

### **Unapproved Devices**



**CAUTION:**

- DO NOT use unapproved devices.
- If the device is connected without the consent of PT. Sinko Prima Alloy, warranty will be INVALID.
- The system cannot be used with HF surgical equipment; burns may occur in the patient.

Each device connected to this system must comply with one or more of the requirements below:

- IEC standard or equivalent standard appropriate for the device.
- The device must be connected to EARTH (GROUND).



**CAUTION:**

Unsafe operation or malfunction may occur. Use only accessories, options and equipment approved or recommended in this manual.

### **Peripheral Used in the Patient Environment**

This system has been verified for safety, compatibility and overall compatibility with the following image recording devices (printers):

Black/white video printer: SONY UP-X898MD

The system can also be used safely when connected to devices other than those recommended above if the device and its specifications, installation, and interconnection with the system comply with the requirements of IEC/EN 60601-1.

Adapter is considered part of ME. equipment

Connections to equipment or transmission lines other than those specified in the user manual may result in an electric shock hazard or equipment malfunction. Replacement or alternative equipment and connections require verification of compatibility and compliance with IEC/EN 60601-1. It is the responsibility of the owner in case of possible malfunctions and electromagnetic interference during the modification of the equipment.

Common precautions in alternate off-board, remote or network installations include:

- The enhancements must comply with safety standards and CE Marking.
- There must be adequate mechanical fitting of the device and stability of the combination.
- The risk and leakage current of the combination shall be in accordance with IEC/EN 60601-1.
- Electromagnetic emission and immunity from combination shall comply with IEC/EN 60601-1-2.

### **Peripheral Used in Non-Patient Environments**

This system has been verified for compatibility, and suitability for connection to a local area network (LAN) via a LAN cable. The LAN components provided must comply with IEC/EN 60601-1.

Common precautions in alternate off-board, remote device or network installations include:

- The enhancements must comply with safety standards and CE Marking.
- The enhancement must be used for its intended purpose with a compatible interface.



**CAUTION:** Be sure to use ONLY special USB disks or removable media for storing or backing up data. Before connecting to the ultrasound system, be sure to use the latest antivirus software such as a USB disk or removable media to clean any viruses. It is the user's responsibility to ensure that the USB disk or removable media is free of viruses. Improper use of USB disks or removable media may result in virus infection of the system which may cause malfunctions. Such damage may impact the stability, effectiveness and safety of the system and probe, and use should be discontinued immediately until an authorized technician has inspected the system and confirmed the effectiveness and safety of the system and probe.



**CAUTION:** Use only secure Local Area Network connections. Do not connect the ultrasound system to the internet. Make sure your hospital's firewall software is properly configured, thus blocking incoming connection requests from the internet. Improper use of network connection can lead to virus infection of the system and eventually malfunction may occur.

## 2.5 Biological Safety

This product, as with all diagnostic ultrasound equipment, must be used only for valid reasons and must be used for the shortest period of time and the lowest power setting required (ALARA – As Low as Reasonably Achievable) to produce an acceptable diagnostic image. AIUM provides the following guidelines:

*Clinical Safety quoted from AIUM*

*Approved March 26, 1997*

*Diagnostic ultrasound has been used since the late 1950s. In light of its known benefits and recognized efficacy for medical diagnosis, including use during pregnancy, the American Institute of Ultrasound in Medicine discusses the clinical safety of such use: No confirmed biologic effects on patient or instrument operator caused by exposure to current diagnostic ultrasound instruments Although it is possible that such biologic effects may be identified in the future, current data suggest that the benefits to patients from using diagnostic ultrasound outweigh the risks.*

**Heating:** Elevating tissue temperature during obstetric examinations can cause medical problems. At this stage of embryonic development, increased temperature and length of time of exposure can have potential adverse effects, especially during Color Doppler/Color Doppler examinations. Thermal Index (TI) provides a statistical estimate of the potential temperature elevation (in Celsius) of the tissue. Thermal Index consists of: Soft Tissue Thermal Index (TIS), Bone Thermal Index (TIB) and Cranial Bone Thermal Index (TIC).

***Soft Tissue Thermal Index (TIS).*** Used for soft tissue imaging only, TIS provides an estimate of the potential for temperature elevation in soft tissue.

***Bone Thermal Index (TIB).*** Used when the bone is near the image focus as in the third trimester OB examination, the TIB provides an estimate of the potential for temperature elevation in the adjacent bone or soft tissue.

***Cranial Bone Thermal Index (TIC).*** Used when bone is in close proximity to the skin surface as in a transcranial

examination, the TIC provides an estimate of the potential temperature increase in the adjacent bone or soft tissue.

**Cavitation:** Cavitation can occur when ultrasound waves pass through a hollow area, such as a gas bubble or air pocket (in the lungs or intestines, for example). During the cavitation process, sound waves can cause the bubbles to contract or resonate. These oscillations can cause the bubble to burst and damage the tissue. The Mechanical Index (MI) has been created to help users accurately evaluate the possibility of cavitation and associated side effects. MI recognizes the importance of non-thermal processes, in particular cavitation, and the Index is an attempt to demonstrate the likelihood of their occurrence within the tissue.

## 2.6 Scanning Patient and Education

The Track-3 or IEC60601-2-37 display output standard allows the user to take responsibility for the safe use of the ultrasound system. Follow the user manual for safe operation:

- To keep the probe clean, always clean it before application to a new patient.
- Always use a disinfected sheath on all EV/ER probes during each examination.
- Move the probe continuously, do not stop in one place, to avoid increasing the temperature in one part of the patient's body.
- Remove the probe from the patient when not performing the scan.
- Understand the meaning of TI, TIS, TIB, TIC and MI display outputs, and the relationship between these parameters and tissue thermal/cavitation bioeffects.
- Use the ALARA (As Low as Reasonably Achievable) principle during scanning.

### Safe Scanning Guidelines

- Ultrasound should only be used for medical diagnosis and only by trained medical personnel.
  - Ultrasound diagnostic procedures should be performed only by personnel trained in the use of the device, interpretation of results and images, and safe use of ultrasound (including knowledge of potential hazards).
  - The operator must understand the possible effect of engine control, operating mode (eg mode B) and probe frequency on heating and cavitation hazards.
  - Select a low setting for each new patient. Output should only be increased during examination if penetration is still required to achieve satisfactory results, and after Gain control is moved to maximum value.
  - Keep examination times as short as necessary to produce useful diagnostic results.
  - Do not hold the probe in the same position for a longer time than necessary. Static and Cine frame capabilities allow images to be reviewed and discussed without requiring the patient to be scanned continuously.
  - Do not use the endo-cavitary probe if there is an indication of heating on the probe when operating in air. While applicable to any probe, provide special care during transvaginal testing during the first eight weeks of pregnancy.
  - Give special care to reduce output and minimize exposure time of the embryo or fetus when the maternal temperature is already high.
  - Provide special care to reduce risk of thermal hazards during ultrasound diagnosis when exposure: embryo less than eight weeks after gestation; or the head, brain or spine of the fetus or neonate.
  - The operator must monitor the thermal index (TI) and mechanical index (MI) values continuously and use control settings that keep the settings as low as possible but still achieve the appropriate diagnostic results. During the obstetrical examination, TIS (soft tissue thermal index) should be monitored during the scan performed in the first eight weeks after pregnancy, and TIB (bone thermal index) thereafter. In operations where the probe is very close to bone (eg trans-cranial), the TIC (cranial bone thermal index) should be monitored.
- MI > 0.3 there is a chance of minor damage to the neonatal lung or gut. If exposure is required, reduce exposure time

as much as possible.

MI > 0.7 there is a risk of cavitation if an ultrasound contrast agent containing gaseous micro-spheres is being used. There is a theoretical risk of cavitation in the absence of an ultrasound contrast agent. The risk will increase if the MI values are above the threshold.

TI > 0.7 the overall exposure time of the embryo or fetus should be limited according to Table 2-2 below for reference:

TI	Maximum exposure time (minutes)
0.7	60
1.0	30
1.5	15
2.0	4
2.5	1

Maximum recommended exposure time for embryo or fetus

- The non-diagnostic use of ultrasound equipment is generally not recommended. Examples of non-diagnostic uses of ultrasound equipment include repeated scans for operator training, demonstration of the equipment using normal subjects, and the production of images or videos of the fetus. For equipment where the displayed safety index exceeds the range of values, TI should always be less than 0.5 and MI should always be less than 0.3. Avoid repeated and too frequent exposure to the subject. Scans in the first trimester of pregnancy should not be performed solely for the production of souvenir videos or photographs, or productions that involve increasing exposure levels or prolonging scan times beyond those required for clinical purposes.
- Diagnostic ultrasound has the potential to produce a false positive or false negative output. Misdiagnosis is far more dangerous than the possible effects of ultrasound exposure. Therefore, ultrasound diagnostic systems should only be operated by those with adequate training and education.

### Understanding MI/IT Display

Track-3 follows the Output Display Standard for systems that include Fetal Doppler applications. Acoustic output will not be evaluated on an application-specific basis, but the global maximum at de-rated Ispta must be 720 mW/cm<sup>2</sup> and global maximum MI must be 1.9 or global maximum at de-rated Isppa must be 190 W/cm<sup>2</sup>. Exception for use on the eye, where TI = max (TIS\_as, TIC) does not exceed 1.0; Ispta.3 50mW/cm<sup>2</sup>, and MI 0.23. The Track-3 gives the user the freedom to increase the acoustic power output in a given test, while still limiting the acoustic power output within the Ispta de-rated maximum global range of 720 mW/cm<sup>2</sup> after the Output Display Standard.

For each diagnostic ultrasonic system, Track-3 provides Standard Output Indices Display. The diagnostic ultrasonic system and operating manual contain information on ALARA (As Low as Reasonably Achievable) education for clinical users and the output of acoustic, MI and TI indices. MI describes the possibility of cavitation, and TI offers a prediction of the maximum temperature rise in the tissue as a result of the diagnostic workup. In general, a temperature increase of 2.5 °C must be present consistently at one point for 2 hours to cause an abnormal fetus. Avoiding a local temperature rise above 1 °C will ensure that no biological effects due to thermal induction occur. When referring to TI for potential thermal effects, TI equal to 1 does not mean the temperature will rise 1 degree Celsius. It just means a potential increase for thermal effects can occur as TI increases. A high index does not mean that a bio-effect is occurring, but simply indicates that there is potential and no consideration was given to the TI during the scan, so minimizing the overall scan time will reduce the potential effect. Operator controls and feature displays shift the responsibility for security from the manufacturer to the user. It is very important for the ultrasound system to display the acoustic index output correctly and educate the user to interpret the values obtained correctly.

**RF: (De-rating factor)**

In situ intensity and pressure can not be measured at this time. Therefore, acoustic power measurements are usually carried out in water tanks, and when soft tissue displaces water along the ultrasound route, there will be a decrease in intensity. The fractional reduction in intensity caused by attenuation is denoted by the de-rating factor (RF),

$$RF = 10 (-0.1 afz)$$

Where  $a$  is the attenuation coefficient in  $\text{dB cm}^{-1} \text{MHz}^{-1}$ ,  $f$  is the center frequency of the transducer, and  $z$  is the distance along the beam axis between the source and the point of interest. The RF de-rating factors for various distances and frequencies with an attenuation coefficient of  $0.3\text{dB cm}^{-1} \text{MHz}^{-1}$  in homogeneous soft tissue are listed in the following table. For example, if the user is using the  $7.5\text{MHz}$  frequency, the power will be attenuated by  $0.0750$  at  $5\text{cm}$ , or  $0.3 \times 7.5 \times 5 = -1.125\text{dB}$ . The de-rated intensity is also referred to as '0.3' at the end (eg  $I_{\text{soft}}/I_{\text{water}}$ ).

Distance (cm)	Frequency (MHz)			
	1	3	5	7.5
1	0.9332	0.8128	0.7080	0.5957
2	0.8710	0.6607	0.5012	0.3548
3	0.8128	0.5370	0.3548	0.2113
4	0.7586	0.4365	0.2512	0.1259
5	0.7080	0.3548	0.1778	0.0750
6	0.6607	0.2884	0.1259	0.0447
7	0.6166	0.2344	0.0891	0.0266
8	0.5754	0.1903	0.0631	0.0158

$$I' = I * RF \text{ where } I' \text{ is the intensity in soft tissue, } I \text{ is the time-averaged intensity measured in water.}$$

**Tissue Models:**

The tissue temperature elevation depends on the power, tissue type, beam width, and scan mode. Six models were developed to mimic possible clinical situations.

	Thermal Model	Composition	Mode	Specification	Application
1	TIS	Soft Tissue	Not scanned	Large aperture ( $>1 \text{ cm}^2$ )	PW Liver
2	TIS	Soft Tissue	Not scanned	Small aperture ( $<1 \text{ cm}^2$ )	Pencil Probes
3	TIS	Soft Tissue	Scanned	Evaluated on surface	Breast color
4	TIB	Soft tissue and bone	Scanned	Soft tissue in surface	Muscle color
5	TIB	Soft tissue and bone	Not scanned	Bones on focus	PW Fetal Head
6	TIC	Soft tissue and bone	Not scanned / scanned	Bone on the surface	Transcranial

Soft tissue:

Describes low-fat tissue that does not contain calcification or is filled with a lot of gas.

Scanned: (auto-scan)

Refers to the system of directing successive exposures through the field of view, e.g. mode B and color.

Unscanned:

The emission of the ultrasonic pulse occurs along one line of sight and does not change until the transducer moves to a new position. For example, PW and M modes.

TI:

TI is defined as the ratio of the In Situ acoustic power (W.3) to the acoustic power required to raise the tissue temperature by 1°C (Wdeg),  $TI = W.3 / Wdeg$ . Three TIs refer to soft tissue (TIS) for the abdomen; bone (TIB) for fetal and neonatal heads; and cranial bones (TIC) for the head of children and adults, have been developed to  $Wdeg = 210/fc$ , for models 1 to 4, where fc is the center frequency in MHz.  $Wdeg = 40/KD$  for models 5 and 6, where K (ray form factor) is 1.0, D is aperture diameter in cm at depth of interest.

MI:

Cavitation is more likely to occur at high pressures and low frequencies in pulsed ultrasound waves in tissues, which contain bubbles or air sacs (e.g., lungs, intestines, or scans with contrast agent gases). The threshold for optimum conditions for the ultrasound pulse is predicted by the ratio of the pressure peak to the square root of the frequency.

$$MI = Pr' / \sqrt{fc}$$

$Pr'$  is the fraction of the de-rated peak (0.3) pressure in MPa at the point where PII is maximum, and fc is the center frequency in MHz. PII is the Pulse Intensity Integral where the total energy per unit area carried by the wave is for the duration of the pulse time. Peak fractional pressure is measured in negative maximum hydrophone voltage normalized with hydrophone calibration parameters.

Display Guidelines:

For different operating modes, different indexes must be displayed. But only one index needs to be displayed at a time. Display is not required if the maximum MI is less than 1.0 for each setting of the operating mode, or if the maximum TI is less than 1.0 for each setting of the operating mode. For TI, if TIS and TIB are greater than 1.0, the scanner does not need to display both indexes at the same time. If the index falls below 0.4, the display is not needed. Display increments of less than 0.2 for index values less than 1.0 and no greater than 1.0 for index values greater than one (e.g. 0.4, 0.6, 0.8, 1, 2, and 3).

Display and Reports

Located at the top center of the monitor screen, the acoustic output display provides the operator with a real-time indication of the acoustic level produced by the system.

For Scan

Displays only MI, from 0.4 if maximum MI > 1.0, display increases by a multiple of 0.2.

Below is a simple guide for users when TI exceeds the one exposure time limit to 4(6-TI) minutes according to the 'National Council on Radiation Protection. Exposure Criteria for Medical Diagnostic Ultrasound: I. Criteria Based on Thermal Mechanisms. Report No. 113 1992'.

**Operator Control Features:**

The user should understand that certain operator settings may affect the acoustic output. It is recommended to use the default output power setting (or lowest output) and compensate using the Gain setting to obtain the image. In addition to setting the output power in the soft-menu, which has a direct impact on power; PRF, image sector size, frame rate, depth, and focal position also slightly affect the output power. The default setting is usually around 70% of the allowable power depending on the measurement mode application.

**Control Affecting Acoustic Output**

The potential to produce mechanical (MI) or thermal (TI) bioeffects can be affected by certain settings.

Direct: The Acoustic Output setting has the most significant effect on the acoustic output.

Indirect: Indirect effects may occur when adjusting settings. The controls that can affect MI and TI are detailed under the bioeffect of each setting in the Image Optimization chapter. Always observe the Acoustic Output display for possible effects.

Best practices when scanning

HINT: Increase Acoustic Output only after attempting image optimization with settings that have no effect on acoustic output, such as Gain and STC.



**WARNING:** Be sure to read and understand the setting descriptions for each mode used before attempting to adjust the Acoustic Output settings or settings that may affect the acoustic output. Use the minimum required acoustic output to obtain the best diagnostic image or measurement during the examination. Begin the examination with a probe that provides optimal depth of focus and penetration.

**Acoustic Output Default Level**

To ensure that the scan does not start at a high output level, the system starts the scan at a reduced default output level. This level is programmed by default and depends on the probe and probe icon selected. The effect takes effect when the system is powered on or New Patient is selected. To modify the acoustic output, adjust the Power Output level on the Soft Menu.

**2.7 Battery Handling Instructions**

**CAUTION:** Read and observe the following warnings and precautions to ensure the correct and safe use of Li-ion batteries.

- Do not immerse the battery in water or allow the battery to get wet.
- Do not use or store the battery near a heat source such as a fire or heater.
- Do not use chargers other than those recommended.
- Do not reverse the positive (+) and negative (-) terminals.
- Do not connect the battery directly to a car receptacle or cigarette lighter socket.

- Do not put the battery in a fire or heat the battery.
- Do not short the battery by connecting wires or other metal objects to the positive (+) and negative (-) terminals.
- Do not punch holes in the battery case with nails or other sharp objects, open with a hammer, or step on the battery.
- Do not hit, throw or give the battery a severe physical shock.
- Do not directly solder the battery terminals.
- Do not attempt to disassemble or modify the battery in any way.
- Do not place the battery in a microwave oven or pressurized container.
- Do not use the battery in combination with a primary battery (such as a dry cell battery) or a battery of a different capacity, type, or brand.
- Do not use the battery if it emits an odor, produces heat, changes shape or color, or looks abnormal. If the battery is being used or is being charged, remove the battery from the device or charger immediately and stop using it.
- Do not use or store the battery in a very hot place, such as under a car window that is exposed to direct sunlight on a hot day. Otherwise, the battery may overheat. It can also reduce battery performance or shorten battery cycle life.  
If the battery leaks and electrolyte get into your eyes, do not rub. Rinse with clean running water and seek medical attention immediately. If left unchecked, electrolytes can cause eye injury.

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## CHAPTER 3 SYSTEM INTRODUCTION

### 3.1 Console Overview



Device Overview

### 3.2 Physical Specification

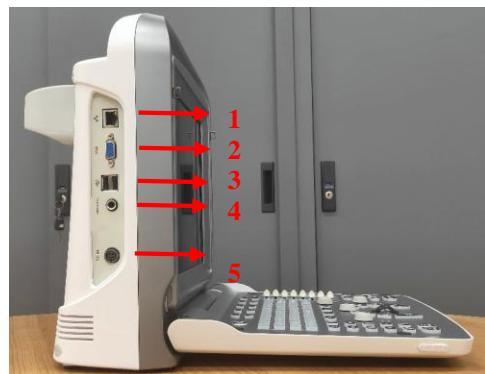
Dimensions of the main unit (approx.): 327 mm (Length) x 184 mm (Width) x 348 mm (Height)

Net weight of main unit (approx.): 6.55 kg

### 3.3 System View in Different Angles



Front View System



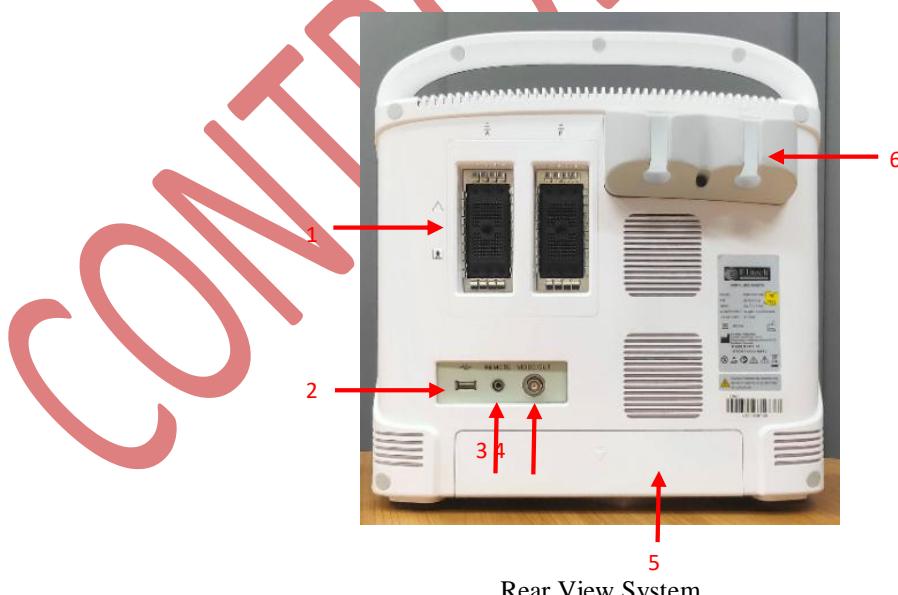
Side View System

1.Ethernet 2.VGA 3.USB 4.FOOT SWITCH 5.DC IN

copy



Keyboard



Rear View System

1. Probe socket 2. USB 3. REMOTE 4. Video Out 5. Battery holder 6. Probe holder

CONTINUE

### 3.4 Function Introduction

1. Has display mode B, B/B, 4B, B/M, M, CFM, PW, M, B/M mode has 4 kinds of scanning speed;
2. Has multiple focus combinations, total gain settings, 8 STC segments;
3. Has depth scan and left-right, up-down, scrolling image functions;
4. Has many imaging technologies eg multiple imaging compound (space frequency compound), various frequency values, various zoom ratio, pan zoom, scroll screen, chroma, harmonic imaging, etc;
5. Has image processing, total gain, dynamic range, frequency, number of focus, focus position, zoom, compound, scan width, line density, smooth, edge enhancement, frame, firmness, gray scale, restrain boost multi-beam, acoustic power, speed M;
6. Has the function of distance, proportion, circumference, volume, rate, angle, histogram in B mode; function of distance, time, speed, heart rate measurement in M mode; GYN measurement software, small organs measurement software, ventricular function measurement software and user-defined formulas;
7. Has body mark, marker, case number display, real-time display time display in user-defined images;
8. It has multi-language display, user interface display, shear plate, printing, DICOM 3.0, biopsy and guided functions;
9. Has permanent storage for images and cine and optional minimum 320GB HDD. Can be connected to removable storage via USB port. For mass storage, can re-open already saved images for analysis;
10. Cine loop real-time image storage 256 frames;
11. The rotation function on the screen allows the user to adjust the screen angle 0~30° according to the user's requirements;
12. Standard output of PAL or NTSC video signal and VGA signal;
13. Print or export a graphical report.

#### **Image mode**

- Mode B
- Mode B / M
- M Mode
- 2B mode
- 4B mode
- CFM Mode
- PW Mode

#### **Accessories**

#### **Transducer**

	C3-A, 2.5-5.0 MHz Convex Array		L7M-A, 5.3-10.0 MHz Linear Array
	L7S-A, 5.3-11.0 MHz Linear Array		V6-A, 4.5-8.0 MHz Micro-convex Array
	R7-A, 5.0-10.0 MHz Linear Array		MC6-A, 4.5-8.0 MHz Micro-convex Array

	MC3-A, 2.5-5.0 MHz Micro-convex Array
---	---------------------------------------

## Peripherals

VGA output for external monitor

VIDEO OUT for black and white video printers

LAN port output

LAN for DICOM and image review

USB 2.0 for flash drives

Foot switch

AC/DC Adapter: MDS-060AAS19 B

Input: 100~240V, 1.5-0.75A, 50/60 Hz

Output: 19V = 3.15A

DELTA ELECTRONICS, INC.

Battery Pack: BT-2500, 4400 mAh.

## 3.5 Installation Procedures



NOTE: Do not turn on the power button until the installation and necessary preparations are complete.

### 3.5.1 Environmental condition

The system must operate in the following environments.

#### 3.5.1.1 Operating Environment Requirement

Ambient Temperature: 5°C ~ 35°C

Relative Humidity: ≤ 80% RH

Atmospheric Pressure: 700hPa ~ 1060hPa

Strong sources of radiation or electromagnetic waves (such as electromagnetic waves from radio broadcasts) can cause image ghosting or noise. The system must be isolated from sources of radiation or electromagnetic waves.

To prevent damage to the system, do not use the device in the following locations:

- Exposed to direct sunlight
- Exposed to sudden changes in temperature
- Dirty
- Vibrating environment
- Close to heat generator
- High humidity

 **NOTES:**

The device generates, uses and can radiate radiofrequency energy. Equipment may cause radiofrequency interference to other medical and non-medical devices and radio communications. To provide protection against such interference, this product complies with the emission limits for Group I, Class A Medical Device Directives as set out in EN 60601-1-2. However, there is no guarantee that interference will not occur in a particular installation.

If this device is found to be causing interference (which can be determined by turning the device on and off), the user (or qualified technician) should try to correct the problem with one or more of the following parameters:

- Change or move the problematic device.
- Improves separation between faulty equipment and devices.
- Turn on the device from a different source with the problematic device.
- Consult a purchasing or service representative for further advice.

#### **3.5.1.2 Transport and Storage Environment Requirements**

The following are delivery and storage environmental conditions within the system tolerances:

Temperature: 10 °C ~ 40 °C

Relative humidity: 30% ~ 75%

Atmospheric pressure: 700hPa~1060hPa

#### **3.5.1.3 Electrical Requirements**

**Power consumption:** less than 60 VA

##### **Voltage Fluctuation**

 **WARNING:**

Keep the fluctuation in the range less than ±10% of the voltage on the label or back panel of the system, otherwise the system may be damaged.

##### **Grounding**

Before connecting the power cord, connect the protective earth wire from the equipotential terminal on the rear panel of the system to the specified grounding device.

 **NOTES:**

- *Follow the stated power requirements. Use only power cables that comply with system guidelines – failure to follow procedures may result in system failure.*
- *The power line may vary in different geographic locations. Refer to the detail rating on the rear panel of the system for detailed information.*
- *Battery*

*To prevent the battery from exploding, burning or smoking; cause damage to the appliance, observe the following precautions: do not immerse the battery in water or allow the battery to get wet; do not place the battery in a microwave oven or pressurized container; do not use the battery if it emits an odor, produces heat, changes shape or color, or looks abnormal; if the battery is in use or is being charged, remove the battery from the device or charger immediately and stop using it, if you have any questions about the battery, short term (less than one month) battery pack storage: Store the battery in a temperature range between 0oC (32oF) and 50oC (122oF).*

*Long-term (3 months or more) battery pack storage: Store the battery in a temperature range between 20oC (-4oF) and 45oC (113oF); After receiving the PRA-ONE and before first use, it is highly recommended that the user performs*

one full cycle of discharging and recharging the battery. If the battery is not used for >2 months, the user is recommended to perform one full cycle of discharging and recharging the battery. It is also recommended to store the battery in a shady and cool place with FCC (full capacity). One Cycle Discharge/Full Charge: 1. Full discharge of battery to let the PRA-ONE turn itself off. 2. Recharge PRA-ONE to 100% FCC (full capacity) 3. Emptying Venue 40 for complete shutdown (emptying takes 1 hour) •When storing packages for more than 6 months, refill packages at least once for 6 months to prevent leakage and performance degradation.

### 3.5.1.4 Operating Space

Allow sufficient free space at the rear of the system to ensure proper ventilation.

 CAUTION: Leave enough free space at the back of the system; otherwise, as the temperature inside the unit increases, damage may occur.

### 3.5.1.5 System Positioning & Transporting

#### Moving the System

When moving or distributing systems, take the precautions described below to ensure maximum safety for personnel, systems and other equipment.

#### Before Moving the System

- Press  for 3 seconds, the system will force shut down and completely shut down the system.
- Disconnect all cables from additional devices (external printers, etc.) from the console.

 NOTES:

- To prevent damage to the power cord, DO NOT pull on the cord excessively or bend the cord when wrapping it.
- Store all probes in their original containers or wrap the probes in a soft cloth or foam to prevent damage.
- Replace gel and other essential accessories in suitable storage containers.
- Make sure that nothing is left on the console

#### When Moving the System

- Carry the system using the handles, or place the system on a trolley to move it.

 NOTES:

Walk slowly and carefully when moving the system.

Do not allow the system to hit walls or doors.

#### Transporting the System

Pay extra attention when dispensing/shipping the system by vehicle. After setting up the system as described above, take the following additional precautions:

- Only use vehicles that are suitable for system delivery.
- Before shipping, place the system in its original storage carton.
- Load and unload systems on surface parked vehicles.
- Load unit into vehicle carefully and according to its center of gravity. Make sure the unit is stationary and upright.
- Ensure that the haulage vehicle can bear the weight of the system plus the passengers.
- Fasten the system firmly using a rope or as directed in the vehicle to prevent movement during shipping. Any movement, coupled with the weight of the system, can cause loose.
- Drive carefully to prevent damage from vibration. Avoid unpaved roads, excessive speed, sudden stops or speeds.

### 3.5.2 Powering the System

#### Acclimatization Time

After delivery, the unit takes 1 hour for every 2.5oC increase if the temperature is below 10oC or above 40oC.



NOTES:

Leave at least 20 to 30 cm of free space behind the system to ensure proper ventilation. Otherwise, as the temperature inside the unit increases, malfunctions may occur.

#### Connecting the electric power

After confirming that the AC power source in the hospital has a normal status, and the AC voltage type matches the power requirements indicated on the system label, connect the power cable to the DC IN socket on the side panel, then connect the cable to the hospital AC mains socket.

Use the power cable provided by the manufacturer, other types of cables are not allowed.

Press for 1 second, the system will boot

Press and a dialog box will appear to turn off the system. Click the enter button to turn it off.

Or press for 3 seconds, the system will force shut down.



Connecting the system to the wrong AC power source can cause system damage or be a hazard to operators and animals.

### 3.5.3 Probe Installation

CAUTION: Only use the probe provided by the manufacturer for this model, probes of other types are not allowed to be used with this system! Otherwise, damage may occur to the system and probe.



Before connecting the probe, check the probe lens, probe cable, and probe connector for abnormal things such as cracks, drops. Abnormal probes are not allowed to be connected to the system; otherwise an electric shock may occur.

- Holding the locking connector on the probe, insert the connector socket vertically.
- Unlock the probe.
- Check the locked probe with one hand to make sure the probe is not loose and is securely connected.



- Only install/remove the probe when the power supply is off, otherwise it will damage the engine or probe
- When installing/removing the probe, place the probe head on the probe holder, this can prevent the probe from falling to the ground.

#### Probe Disassembly

Turn the latch 90 degrees counterclockwise, pulling the probe connector vertically.

### 3.5.4 Accessories Installation

**⚠️ WARNING:** Only use optional parts supplied or recommended by the manufacturer! Using other types of optional devices may cause damage to the system and connected optional devices.

#### Video Printer Installation

1. Place the video printer in a stable place.
2. Connect the printer's video cable to the video port on the back of the printer. Connect the other end to the signal output port on the back of the unit.
3. Connect the printer line to the printer control port on the back of the printer, connect the other end to the printer control port on the back of the unit.
4. Connect the power cable from the video printer to a power source.
5. Adjust printer parameter presets based on the type of printer paper.

**⚠️ CAUTION:** Do not use another power cord to replace the 3-Line power cord provided by the manufacturer, otherwise there is a danger of electric shock.

#### Symbol on Video Printer

-  : Video signal input port
-  : Video signal output port
-  : Printer control port
-  : Printer video button

#### Graphic Printer Installation

Place the graphics printer in a stable place, connect the printer cable to the USB port on the left side of the unit.

Connect the power cable from the graphics printer to a power source.

**⚠️ WARNING:** See packing list for fundamental configuration!

## CHAPTER 4 CONTROL PANEL

### 4.1 Alphanumeric Keyboard



Alphanumeric Keyboard

Alphanumeric keys are used for input of patient numbers, names, characters, and pictures, etc.

### 4.2 Function Button

#### 4.2.1 Switch



Turn the device on or off.

#### 4.2.2 Patient



Create new patient data, input name and other information.

#### 4.2.3 Probes



Press this button to select a probe. Can only select connected probes.

#### 4.2.4 Setup



Press this button to enter or exit the system setup page.

#### 4.2.5 End



Press the END button to complete the examination.

#### 4.2.6 Bodymark



Press this button to enter the working status of the bodymark, select the bodymark and confirm the scan probe position on the screen. It is only available in freeze state.

#### 4.2.7 Comment



Press this button to enter the comment status, and add a comment to the image field on the screen.

#### 4.2.8 Arrow



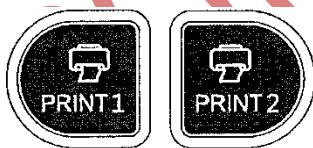
Added arrow icon to drawing area.

#### 4.2.9 Del



Press this button to delete measurement lines, bodymarks, and comments.

#### 4.2.10 Print



PRINT1: Prints a screen image with a video printer connected to the system.

PRINT2: Prints a report by the printer connected to the system (Only the report page is active). Or print the image on the scan page; Or print the image on the review page.

#### 4.2.11 Archive



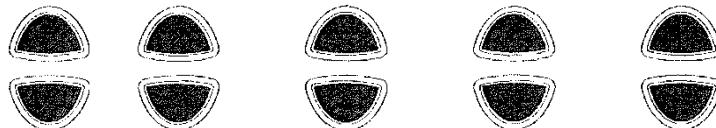
File management of the system, you can view and edit patient data.

#### 4.2.12 Report



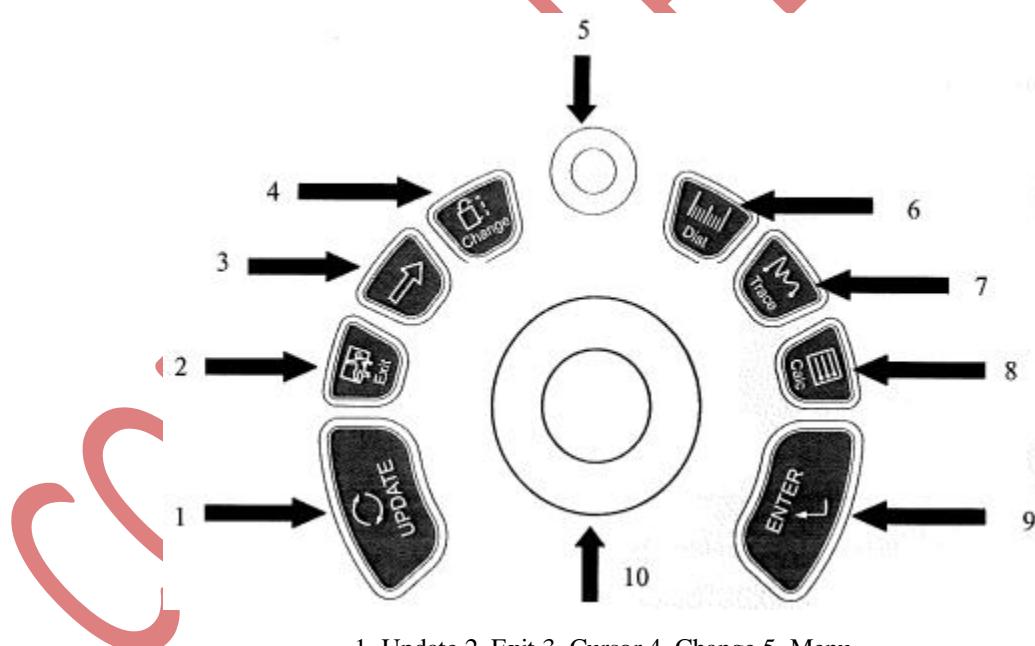
Generate/save/recall examination report.

#### 4.2.13 Parameter Control Button



Increases/decreases the appropriate parameter on the screen, or opens/closes the function.

### 4.3 Central Control



**4.3.1 Enter**

This multifunction button works with the trackball. Its function is to change the status of the unit. Such as, adjust the cursor position, bodymark position, comment position, switch trackball functions, select menus, and confirm input.

**4.3.2 Update**

This multifunction button works with the trackball. Its function is to change the status of the unit. Like, calling the annotation and going back to the measurement.

**4.3.3 Exit**

Pressing this button can exit measurements, dialogs, and menus.

**4.3.4 Cursor**

Press this button to show or hide the cursor.

**4.3.5 Change**

Press this button to change the menu.

**4.3.6 Dist**

Press this button to enter the distance measurement.

**4.3.7 Trace**

Press this button to enter the trace measurement, and press [Update] to change the trace and ellipse.

**4.3.8 Calc**

Press this button to enter the measurement software.

**4.3.9 Menu**

Press the MENU button a second time to select items and adjust parameters. Press the MENU button a third time to exit the current item. Turn the menu dial to select an item.

**4.3.10 Trackball**

*trackball* is the main operating tool on the screen. The position of the caliper in the measurement, the function of the trackball is different in different working status.

**4.4 Image Mode Button****4.4.1 B**

B tampilan display mode

**4.4.2 C**

CFM display mode

#### 4.4.3 D



PW display mode

#### 4.4.4 M



Press this button to change the mode between B/ M and M.

### 4.5 Image Settings

#### 4.5.1 THI



Press this button to open or close the THI function.

#### 4.5.2 AIO



Just press this button for automatic image optimization.

#### 4.5.3 CINE



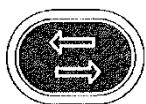
Just press this button to save the current cine loop.

#### 4.5.4 Save



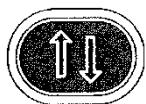
Just press this button to save the current image.

#### 4.5.5 Right and Left Invert



Press this button to flip the image from left and right.

#### 4.5.6 Up and Down Invert



Press this button to flip the image from top and bottom.

#### 4.5.7 STC



STC can be used to adjust gain compensation at different image depths.

#### 4.5.8 Gain

Turn the knob to adjust the gain of mode B and mode M.

#### 4.5.9 Angle/ Zoom Button

Turn the dial to adjust the angle or zoom. Press this button to change the function between angle and zoom.

#### 4.5.10 Depth/Focus Button

Press the button to adjust the depth and position of the function. Press the button to change the function between depth and focus position.

#### 4.5.11 Information Area Indicating Machine Status



Top row from left to right: hard disk, cable network, USB.

- *Hard disk*: press this icon to indicate the capacity of the hard disk used to store data or the USB flash disk in the current system.
- *Cable network*: shows the current situation of the wired network; press this icon to show the IP address of the current system.
- *USB*: indicates whether the system is connected to a USB flash disk or not, press this icon to indicate the USB interface can be safely removed.

Bottom row from left to right: Case, Task Sequence, Battery indicator.

- *Case*: press this icon to change examination.
- *Task Sequence*: press this icon to show the job and its situation, to end the job, delete, and so on.
- *Battery indicator*: shows battery connection situation, press this icon to show charge and discharge status, remaining power and remaining time on battery.

#### 4.5.12 Light Indicator



From left to right: adapter indicator, charging indicator, and sleep indicator.

- *Adapter Indicator*: when the unit is connected with the adapter to the power source, the indicator light is on, otherwise the indicator light will be off.
- *Charging Indicator*: when the battery is charging, the indicator light is on, after the battery is charged, the indicator is off.
- *Sleep indicator*: when the main unit is in sleep mode, the indicator light is on, otherwise the light is off.

## CHAPTER 5 OPERATION AND EXAM MODE

This chapter mainly describes the normal operating processes of the device, including preparation before examination, how to obtain images, optimize images, add comments, bodymarks and so on.

### 5.1 System Preparation before Use

#### Device Inspection

1. The device is placed in a stable place;
2. Grid voltage AC 100-240V, 50/60Hz;
3. Cable is properly connected, firm, and ground, adapter is properly connected to device;
4. The probe is connected and fixed.

#### Power ON



Press for 1 second to start the machine, wait for the system to enter the user interface, turn the probe slot into mode B.

### 5.2 Choose Exam Mode

#### Probe Identification

The system default automatically identifies the current probe type, when the probe is inserted, press to switch probes.



**WARNING:** Only connect or remove probes after the system is frozen to ensure stability and prolong probe life.

#### Mode Selection

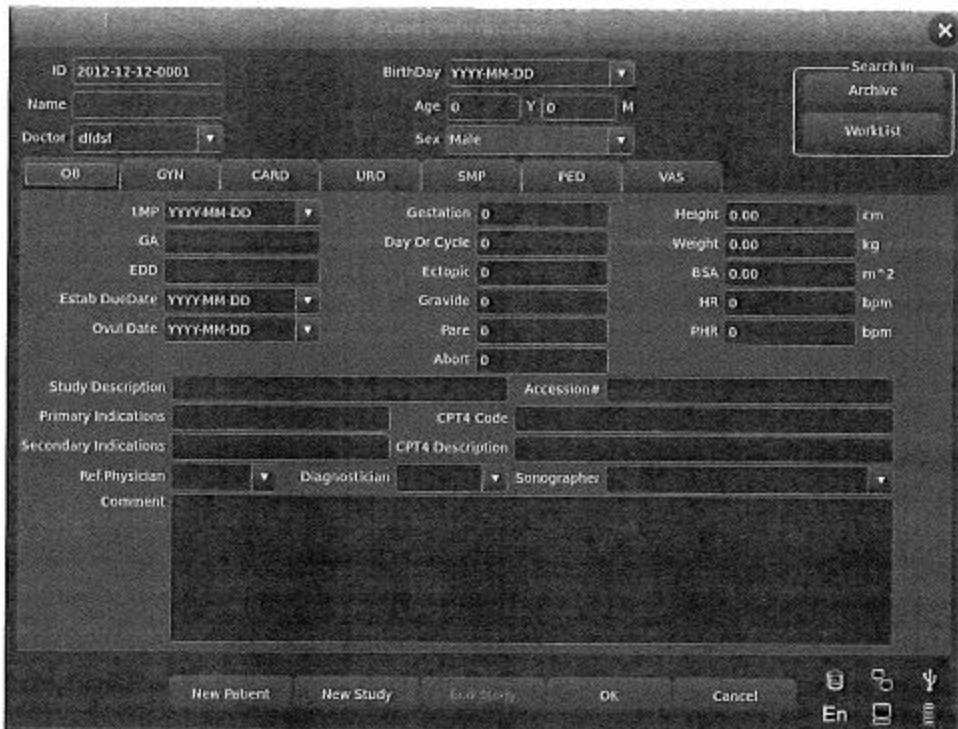
The probe selection interface, probe and clinical application selection page is displayed, you can select the required probe and exam section, and press the default to mode B, start scanning.



**NOTE:** The system has preset clinical application presets before leaving the factory, each probe has its own preset. The detailed operating steps of the clinical application preset of the probe, please refer to the PRESET section.

### 5.3 Patient Data Entry

Press the button  to display the patient view



Patient Information Screen

#### Function Button on Patient Screen

**[Archive]:** Operations on existing patient information;

**[Worklist]:** Recall patient information in the worklist. And need to open DICOM function;

**[New Patient]:** Create new patient information identity;

**[New Study]:** Select examination application (OB, GYN, CARD and so on) for new patients;

**[End Study]:** Edit patient examination items;

**[OK]:** Store patient information;

**[Cancel]:** Cancel operation of new patient information;

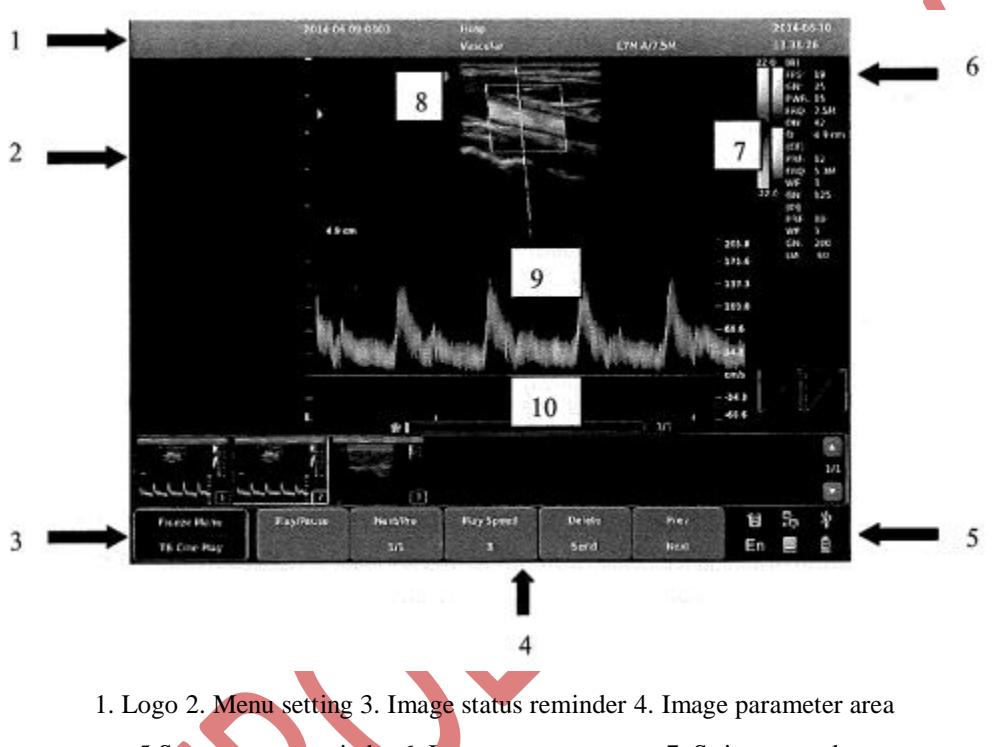
#### Operation method:

- 1.Move trackball position to enter characters, input patient information with keyboard characters.
- 2.Use the trackball and the **[ENTER]** key to switch between various input options: ID, patient name, doctor name, birthday (It can be calculated automatically when input age), age (It can be automatically calculated when date of birth is entered), gender.
- 3.Select an examination item, and enter routine examination information.
- 4.After entering the required information, click the **[OK]** button to save the patient information, the system will return to mode B.
- 5.To recall information from a previous patient, you can use Archive or Worklist to recall patient information for examination.



**NOTE:** To create a diagnostic record, you must check the accuracy of the patient information before saving measurements or images; otherwise it will be saved on the wrong recording. After examining the patient, press the [END] key to save the patient information in the system.

#### 5.4 Image Interface Display



#### 5.5 Display Mode

Display mode: B, 2B, 4B, M, B/M, mode can be changed by mode button.

##### 5.5.1 B Mode

Press the mode button [B], and display a single B mode image, B mode is the basic mode for two-dimensional scanning and diagnosis.

##### 5.5.2 B/B Mode

Press [2B] to display two B mode images side by side. One of the images is in real-time status; the other is in a freeze state. Real-time images have scan markers and ruler markers. Press button 2B in B/B mode, the active initial image is in freeze state while the freeze initial image is activated. In freeze state, press [2B] to select the B mode image to be activated when turning off image freeze.

### 5.5.3 4B Mode

Press [4B] button to enter 4B mode, the screen will display 4B mode images side by side, but only one image in real-time status. Press the button again to switch real-time status among the four images. In freeze state, press [4B] to select the B mode image to be activated when deactivating image freeze.

### 5.5.4 B/M Mode

Press the [B/M] button, the B mode real time image and M mode real time image will be displayed at the same time. A sample line will appear in the B mode image area, indicating the current sample position for the M image in the B image area. Move the sampling line with the trackball.

### 5.5.5 M Mode

Press the [M] button again, the B mode image will disappear; M mode image is still active on the whole screen. The M mode image represents the tissue movement status in the sampling line. The M mode image varies with time, so it is often used for cardiac applications.

### 5.5.6 CFM Mode

CFM is a Doppler mode that is intended to add color-coded qualitative information about the relative velocity and direction of fluid motion in B mode images. CFM is useful for viewing flow over a wide area. This allows the visualization of flow at CROI, while the Doppler mode provides spectral information over a smaller area. CFM is also used as a stepping stone to Doppler mode. You can use CFM to search for flows and vessels before activating Doppler mode.

In CFM mode, the trackball moves to change the position of the sampling box. Activate [Steering Angle] and turn the [MENU] knob to adjust the angle of the colored sampling box (if the current probe is linear probe). Press the [ENTER] key to correct the sampling position of the colored sample box. At that time, adjust the size of the colored sample box through the motion of the trackball. Press the [ENTER] key again and move the trackball to change the color sampling position again. Press [C] to enter CFM mode; after the [C] button light is on, turn the [GAIN] dial to adjust the gain of the CFM.

#### **CFM mode Exam Procedure:**

- Follow the same procedure as described in mode B to locate the desired anatomical area.
- After optimizing the B mode image, add Color Flow.
- Move the color region of interest CROI as close to the center of the image as possible.
- Optimize color flow parameters so that high frame rates can be achieved and precise flow rates can be visualized.
- Press the [FREEZE] button to hold the image in cine memory.
- Record the required color flow images.

#### **CFM Scanning Hints:**

**PRF:** increase/decrease PRF on color bar. Higher velocity flow imaging requires increasing the velocity scale value to avoid aliasing

**Wall Filters:** affect low flow sensitivity to motion artifacts

**Colormaps:** allows you to select a specific color map. It shows the direction of flow and highlights the higher speed currents.

**Color Gain:** increase the overall power of the echo process in CROI

**Persistence:** affects temporal smoothing and color Doppler strength

### 5.5.7 PW Mode

Doppler is intended to provide measurement data regarding the speed at which tissues and fluids move. PW Doppler allows you to examine selective blood flow data from a small area called a Volume Sample. The X axis represents time while the Y axis represents velocity either forward or reverse. PW Doppler is commonly used to display the velocity, direction, and spectral content of blood flow at selected anatomic sites. PW Doppler can be combined with mode B for fast selection of anatomic areas for PW Doppler examination. The area where the PW Doppler data originates will display a B mode image graphically (Sampling Volume Gate). The Volume Gate sample can be moved anywhere in the B mode drawing.

#### PW mode Exam procedure:

- Get a good B mode image. Press the [C] key to help locate the vessel you want to examine.
- Press the [D] key to display the volume and gate sample cursors.
- Position the sample volume cursor by moving the trackball left and right. Position or re-measure the gate sample volume by moving the trackball up and down, then press [ENTER].
- Press [Update] to display the PW Doppler spectrum and the system will run in combined Doppler+B mode. The Doppler signal can be heard through the speakers.
- Optimize the PW Doppler spectrum as needed.
- Make sure that the sample line is parallel to the blood flow.
- Press [FREEZE] to hold the trace in the cine memory and stop imaging.
- Do measurements and calculations, if necessary.
- Record results with your recording device.
- Press [FREEZE] to continue imaging.
- Repeat the above procedure until all relevant flow areas have been examined.
- Place the probes in their respective holders.

When entering Duplex mode for the first time, the Doppler spectrum is not yet activated. The Volume Sample Doppler appears at the default position, and the B or 2D image mode (either B or Color) is active. Moving the trackball changes the position of the Volume Sample. Press the [ENTER] key to toggle the trackball function between Volume Gate Sample and measure. Press the [Update] button after the Volume Gate Sample is used to activate Spectral Doppler mode. Press the [Update] button a second time to switch back to 2D (B or Color) and disable Spectral Doppler.

#### Doppler mode scanning tips:

The best Doppler data will be obtained when the scanning direction is parallel to the direction of blood flow; when the scan direction is perpendicular to the anatomical target, you can get the best B mode images, so you have to maintain a balance because you don't usually get both ideal B mode images and ideal Doppler data at the same time.

**PRF:** adjusts the speed scale to accommodate faster/slower speeds of blood flow. The speed scale determines the frequency of pulse repetition.

**Wall Filters:** eliminates noise caused by vessel wall or heart movement by decreasing flow sensitivity.

**Baseline:** adjusts baseline to accommodate faster or slower blood flow to eliminate aliasing.

**Angle:** optimizes flow velocity accuracy. Angle will estimate the flow velocity at an angle to the Doppler vector by calculating the angle between the Doppler vector and the flow to be measured. It is specially used in vascular applications where you need to measure velocity.

**Doppler Gain:** allows you to control the background spectral information.

**Sweep Speed:** speed control of spectral update.

## Volume Gate Sample Doppler Position and Size (Trackball and ENTER)

Move the sample volume in B mode in the Doppler cursor. The gate is positioned above a certain area in the blood vessel.

- To move the Doppler cursor position, move the trackball left or right until it is above the blood vessel.
- To move the sample volume gate position, move the trackball up or down until it is positioned in the vessel.
- To set the gate volume sample size, press [ENTER] to switch the trackball function from the gate sample volume position to size, then move the trackball to change the gate sample volume size.

## 5.6 B Image Adjustment

### 5.6.1 Frequency

In real-time state, press the first row button [Frequency] to increase the frequency, and press the second row button [Frequency] to decrease the frequency.

### 5.6.2 Dynamic

Dynamic range is used to adjust B mode image contrast resolution, compression or enlarge the greyscale display range.

In real-time state, press the first row button [Dynamic] to increase Dynamic, and press the second row button [Dynamic] to decrease Dynamic. Has a range from 30 to 90.

### 5.6.3 i-Image

In real-time state, press the corresponding button with [i-Image] to adjust, the range is from 0 – 3.

### 5.6.4 Compound

In real-time state, press the corresponding button with [Compound] to adjust, the range is from 0 – 3. SRA cannot be edited after opening compound.

### 5.6.5 SRA

In real-time state, press the corresponding button [SRA] to enable or disable.

### 5.6.6 M . Speed Adjustment

In real-time M state, press the corresponding button with [Speed] to adjust the M speed, range from 1– 4.

### 5.6.7 Gain

In real-time state, turn the [GAIN] knob to adjust the Gain, the range is from 0-255, the increment is 5.

### 5.6.8 STC

The STC curve can be used to adjust the gain compensation at different depths. Drag the STC slide to adjust the values.

The STC curve will disappear automatically 1 second after the adjustment stops.

### 5.6.9 Depth

Press the [DEPTH/FOCUS] selection button until the [DEPTH] indicator lights up, then rotate the dial to change the image depth.

### 5.6.10 Focus Position

Press the selection button [DEPTH/FOCUS] until the [FOCUS] indicator lights up, then turn the knob to change the focus position.

### 5.6.11 Angle

Change the sampling line angle of the sampling gate in PW mode.

Press [ANGLE/ZOOM] make sure the ANGLE lamp is on, the sample line rotates in the same direction.

### 5.6.12 Angle/ Zoom

Press the [ANGLE/ZOOM] button until the [ANGLE] indicator lights up, and the sample gate angle will rotate in the direction of rotation.

Press [ANGLE/ZOOM] to confirm the [ZOOM] button is on, and a zoom box will appear, turn the knob to select the zoom.

### 5.6.13 Invert

B mode images and B/ M mode images can be flipped horizontally and vertically.

Press the button  , the displayed image is reversed in a right-left horizontal direction. Press the button  , the displayed image is reversed in a vertical up-down direction.

The horizontal reversal status indicator on the top left of the drawing window has the following meaning

The meaning of the symbol "O" indicates the initial scan position. The "O" located on the left indicates that the first scan line on the left of the screen corresponds to the initial scan probe position,

The "O" located on the right indicates that the first scan line on the right of the screen corresponds to the initial scanning probe position.

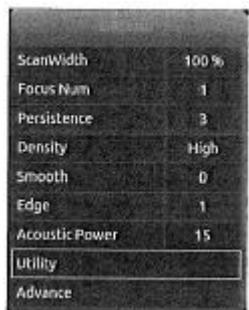
### 5.6.14 THI

Turn on/off THI.

### 5.6.15 AIO

Press this button only for image optimization.

## 5.7 B Image Menu Adjustment



Click the [Change] or [MENU] button to display the menu.

Turn the [MENU] dial or press [Cursor] to display the cursor, and move the sample box according to the function, press [MENU] to update the function, then turn the [MENU] dial to adjust the function, press [MENU] again to exit the function.

### 5.7.1 Scan Width

Select [Scan Width], and adjust the scan width.

### 5.7.2 Focus Num

In mode B, 4 focus points can be selected alternately, and the number is controlled by depth, SRA and Compound.

Move the cursor to the [Focus Num] selection to adjust, it has a range of 1 – 4. When Compound or SRA is active, the focus number can be adjusted to 2 (maximum).

### 5.7.3 Persistence

In real state, it is used to adjust contrast and resolution.

In real state, press the first row button [Persistence] to adjust. Has a range of 0 – 7.

### 5.7.4 Line Density

The scan path density function only applies to images in B mode, B/ B mode, B/ M or 4B mode. Line density has two types: high density and low density. High density means better image quality while low density means higher frame rate. For make adjustments, select the [Density] submenu item and press [MENU] to set the line density.

### 5.7.5 Smooth

The smoothness function is used to suppress image noise and performs the axial smoothing process to make the image better.

Move selection cursor [Smooth] for adjustment, range from 0 – 7.

### 5.7.6 Edge Enhance

Edge enhancement is used to enhance the outline of an image. In this way users can see the tissue structure more clearly.

Move cursor [Edge] to adjust, range from 0 – 7.

### 5.7.7 Acoustic Power

Acoustic power is the acoustic power transmitted from the probe.

In real-time status, move the cursor to **[Acoustic Power]** to adjust.

### 5.7.8 Utility

This function includes post processing, slide show and other items. Press **[MENU]**, then select the Utility selection, the Utility options will appear.

#### Post processing

##### 5.7.8.1 Chroma

Adjust the chroma type.

Select **[Chroma]**, and turn **[MENU]** to select the Chroma type, range from 0 – 39.

##### 5.7.8.2 2D Map

Choose a scale curve type.

Select **[2D Map]**, and rotate **[MENU]** to select the scale curve type, range from 1 – 4.

##### 5.7.8.3 B Gamma

Adjusts the grayscale image parameters.

Select **[B Gamma]**, and turn **[MENU]** to select the B Gamma parameter, range from 0 – 8.

##### 5.7.8.4 B Rejection

Adjusts the inhibition of the grayscale image parameters.

Select **[B Rejection]**, and turn **[MENU]** to adjust the B Rejection parameter, range from 0 – 256.

### 5.7.9 Advance

In mode B, select Advance, after pressing the **[MENU]** button, the Advance option will appear.

#### 5.7.9.1 Zoom Coef

Adjust the size of the ruler and drawing.

Select **[Zoom Coef]**, and turn **[MENU]** to adjust, range from 60% - 100%.

#### 5.7.9.2 MB

Open via MB to improve image quality.

Press **[MENU]** to turn the MB function on or off.

#### 5.7.9.3 Trapezoidal Mode

Press **[MENU]** to turn the trapezoidal function on or off. This function is activated by a linear probe.

#### 5.7.9.4 Biopsy

Show or hide the biopsy.

Press the **[MENU]** key to show or hide the biopsy line.

After the biopsy line is displayed, press the **[ENTER]** key to activate the biopsy line adjustment function, rotating the trackball horizontally can translate the biopsy line, vertically can adjust the line angle, press **[Update]** to set the biopsy line default position.

### Accessories

To order a biopsy guide; or other supplies and accessories, contact CIVCO Medical Solutions:

CIVCO Medical Solutions

102 First Street South, Kalona, IA 52,247-9,589

Telephone: 800-445-6741 (United States and Canada), +1 319-656-4447 (International)

Fax: 877-329-2482 (United States and Canada), +1 319-656-4451  
 (International) E-mail: info@civco.com

Internet: www.civco.com

## NOTES:

Models or part numbers in the following table are subject to change.

Biopsy guide

Transducer	Compatible Biopsy Model Guide
V6-A	610-1093 (10041823)

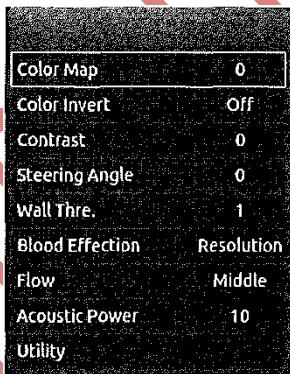
### 5.7.9.5 Center Line

Show or hide the center line.

Press the [MENU] key to show or hide the center line.

## 5.8 CFM Image Adjustment

Parameters in Color mode:



### 5.8.1 Color Map

Changing the Color Map type

Activate [Map Color] and turn [MENU] to adjust Color Map, adjustment has a range from 0– 8.

### 5.8.2 Color Invert

Reverses the color of the blood stream.

Activate [Color Invert] and turn [MENU] to turn on or off, or press  to invert the colors.

### 5.8.3 Contrast

Adjust the color contrast.

Activate [Contrast] and turn [MENU] to adjust contrast, adjustment ranges from 0 – 8.

#### 5.8.4 Steering Angle

Adjust the steering angle.

Activate [Steering Angle] and turn [MENU] to adjust the steering angle, it has a range of -10/-5/0/5/10.

#### 5.8.5 Wall Thre.

Activate [Wall Thre.] and turn [MENU] to adjust wall boundary., adjustment range from 0 – 14.

#### 5.8.6 Blood Effect

Activate [Blood Effect] and turn [MENU] to adjust the blood effect, adjustment has a fine/resolution range.

#### 5.8.7 Flow

Set the flow rate.

Turn on [Flow] and turn [MENU] to adjust the flow, the adjustment has a low/medium/high range.

#### 5.8.8 Freq

Sets the frequency of the Color mode.

Press the parameter control button on [Freq] to change the frequency, the range depends on the probe type.

#### 5.8.9 Wall Filter

Adjust the color contrast.

Press the parameter control button on [Wall Filter] to change the filter wall, adjustment has a range from 0 – 3.

#### 5.8.10 PRF

Set up PRF.

Activate [PRF] and turn [MENU] to adjust PRF, adjustment has a range from 0 – 15.

#### 5.8.11 Persistence

Set robustness.

Activate [Persistence] and turn [MENU] to adjust the toughness, the adjustment ranges from 0 – 7.

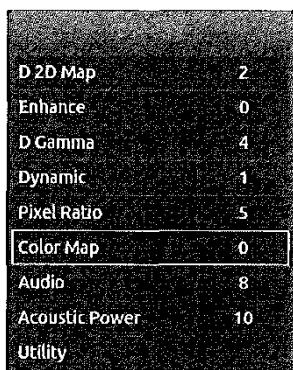
#### 5.8.12 Baseline

Set the baseline position.

Press v parameter control button on [Baseline] to change the baseline position, the adjustment has a range from 0 – 6.

## 5.9 PW Image Adjustment

Parameters in PW mode:



### 5.9.1 D 2D Map

Customized 2D D maps.

Activate D 2D and turn the [MENU] adjustment has a range of 1/2/3/4.

### 5.9.2 Enhance

Adjusting upgrades.

Activate [Enhance] and turn [MENU] to adjust the increase, the adjustment has a range from 0– 3.

### 5.9.3 D Gamma

Adjusted D Gamma.

Activate D Gamma and turn [MENU] to adjust D Gamma, adjustment has a range from 0 – 8.

### 5.9.4 Dynamic

Set dynamic.

Activate [Dynamic] and turn [MENU] to set dynamic, has a range of 0 – 7.

### 5.9.5 Pixel Ratio

Sets the pixel ratio.

Activate [Pixel Ratio] and rotate [MENU] to adjust the pixel ratio, adjustment range from 0 – 7.

### 5.9.6 Color Map

Change the color map type.

Activate [Color Map] and turn [MENU] to set the color map D, adjustment has a range from 0– 8.

### 5.9.7 Audio

Adjust the audio volume.

Turn on [Audio] and turn [MENU] to adjust the audio volume, the adjustment has a range of 0 – 15.

### 5.9.8 Acoustic Power

Change the acoustic power.

Turn on [Acoustic Power] and turn [MENU] to adjust the acoustic power, the adjustment has a range of 0 – 10.

### 5.9.9 Invert

Press the parameter control button on [Invert] or press or press to reverse the spectrum.

### 5.9.10 Wall Filter

Press the parameter button on [Wall Filter] to adjust the wall filter, the adjustment has a range from 0 – 3.

**5.9.11 Speed**

Press the parameter button on [Speed] to adjust the speed, the adjustment has a range from 0–2.

**5.9.12 PRF**

Set up PRF.

Press the parameter button on [PRF] to adjust the PRF, the adjustment has a range from 0 – 15.

**5.8.13 Baseline**

Set the baseline position.

Press v parameter control button on [Baseline] to change the baseline position, the adjustment has a range from 0 – 6.

**5.10 Full Screen Show (need to activate this function in setup)**

Displays full screen / full screen in the image area. Press [GAIN] to activate the function; Press [EXIT] or [GAIN] again to exit the full screen display.

When the full screen is displayed, press [MENU] to display the menu of the current mode (except bodymark).

**5.11 Edit Comment****5.11.1 Overview**

Comments are used to enter text or symbols in images, the device has an English and Chinese annotation system.

Enter a comment: Press  go to comment status;

Exit comments: Press  back or [FREEZE] to exit;

Comments are intended to include words or symbols in the image as an explanation. Adding comments can be via direct keyboard input or using the default comments.

The default comments are classified by exam mode as follows:

Classification	Function Description
Abdomen	Abdomen, general anatomy terminology
Obstetrics	Anatomical terminology from obstetrics
Gynecology	Anatomical terminology from gynecology
Heart	Anatomical terminology of the heart
Small Organ	Anatomical terminology of small organs
Pathological Changes	Anatomical terminology of pathological changes



**NOTES:** If you wish to change the default comments, please refer to the presets section.

**5.11.2 Input Characters**

Operation:

1. Press the button , the system will enter the comment process.
2. Move the cursor to the position that requires the comment.
3. Enter the character at the cursor position with the keyboard then press [ENTER] to confirm.
4. Press  back to get out. Button light  will be off and the commenting process is complete.

### 5.11.3 Input Comment Library Character

1. In the comment status, move the trackball over the image area to edit;
2. Press [Font size] to adjust the size of the comment text, it has a range of 10 – 20.
3. Turn [MENU] to select the desired comment, then press [MENU] to exit;

### 5.11.4 Edit Quick Comment

1. Press [Edit] to bring up the quick comment edit box;
2. Enter the desired comment;
3. Press [Done] to finish editing, press [X] to cancel edit;

### 5.11.5 Input Quick Comments

1. Press [Text] to select the required quick comment;
2. Adjust the post size of the comments;
3. Press [Input] to place a comment on the image field;

### 5.11.6 Move Comments

1. In the comment status, move the trackball to the comment, press [ENTER] to activate;
2. Move the trackball to place comments on the target area;
3. Press [ENTER] again to confirm the comment;

### 5.11.7 Edit Comment

1. In the comment status, move the trackball to the comment, press [ENTER] to activate;
2. Press [BACKSPACE] to delete unnecessary comments;
3. Press [ENTER] to confirm the comment;

### 5.11.8 Delete Comments

#### 5.11.8.1 Delete Characters

In the comment status, activate the comment that needs to be deleted, then press [ENTER], symbol “|” will be displayed on the screen, press [BACKSPACE] to delete the character.

#### 5.11.8.2 Delete Single Comment

Activate the comment that needs to be deleted, then press [DEL] to delete the comment.

#### 5.11.8.3 Delete All Content Comments

Do not enable single comment, press [DEL] to delete all characters that have input.



**WARNING:** Press the [DEL] key, but it will clear the measurement and bodymark at the same time.

### 5.11.9 Set the Default Comment Position

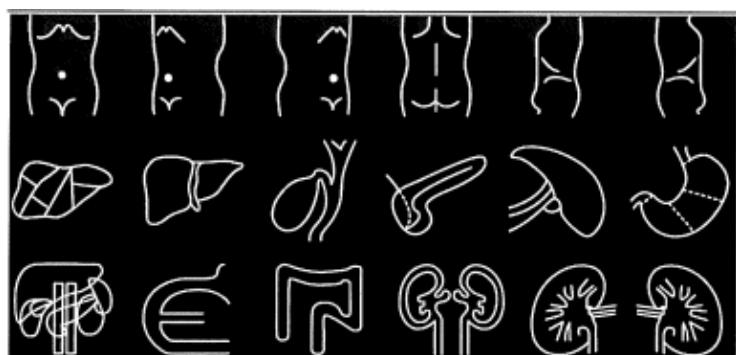
Operation:

1. Press [Save Home Pos.] to move the cursor to the initial position;
2. Press [Load Home Pos.] to set the initial position;

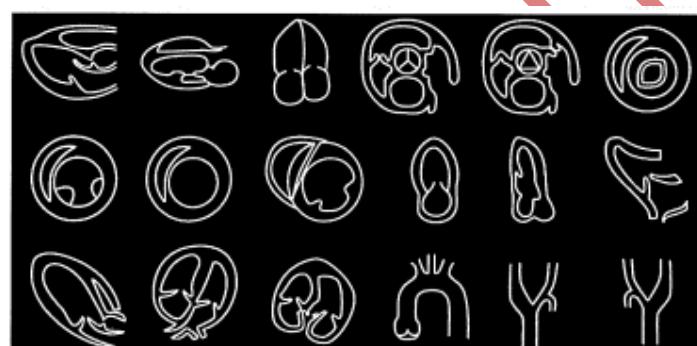
### 5.12 Set Bodymark

#### 5.12.1 General Description

*Bodymark* indicates the patient's examination position and the direction of the scanning probe on the image. Bodymarks are divided into: obstetrics, abdomen, gynecology, heart and small organs etc., each has a different bodymark. Each type of bodymark automatically corresponds to the current exam mode. Icon:



Abdomen Mark

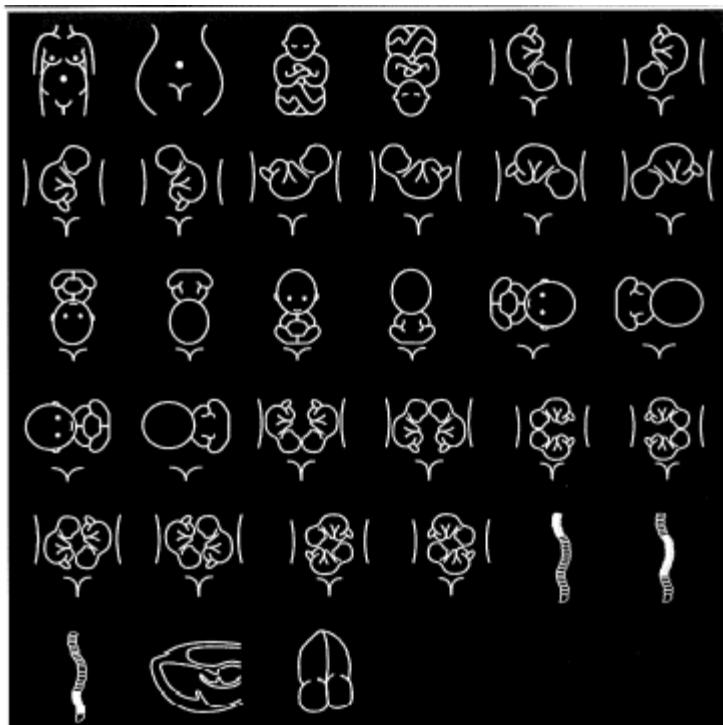


Cardiac Mark



Urology Mark

Red diagonal watermark: DRAFT COPY



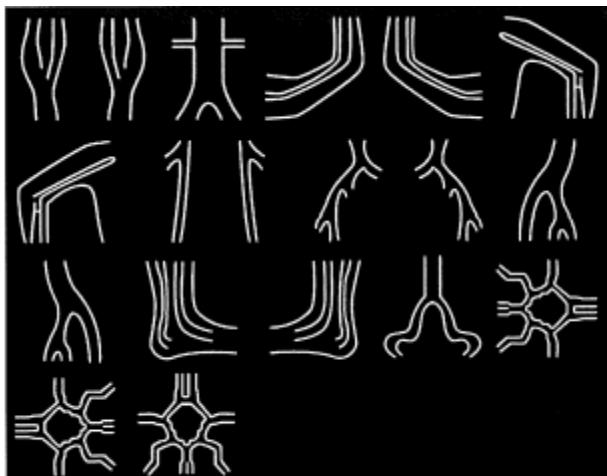
Obstetric Mark



Gynecology Mark

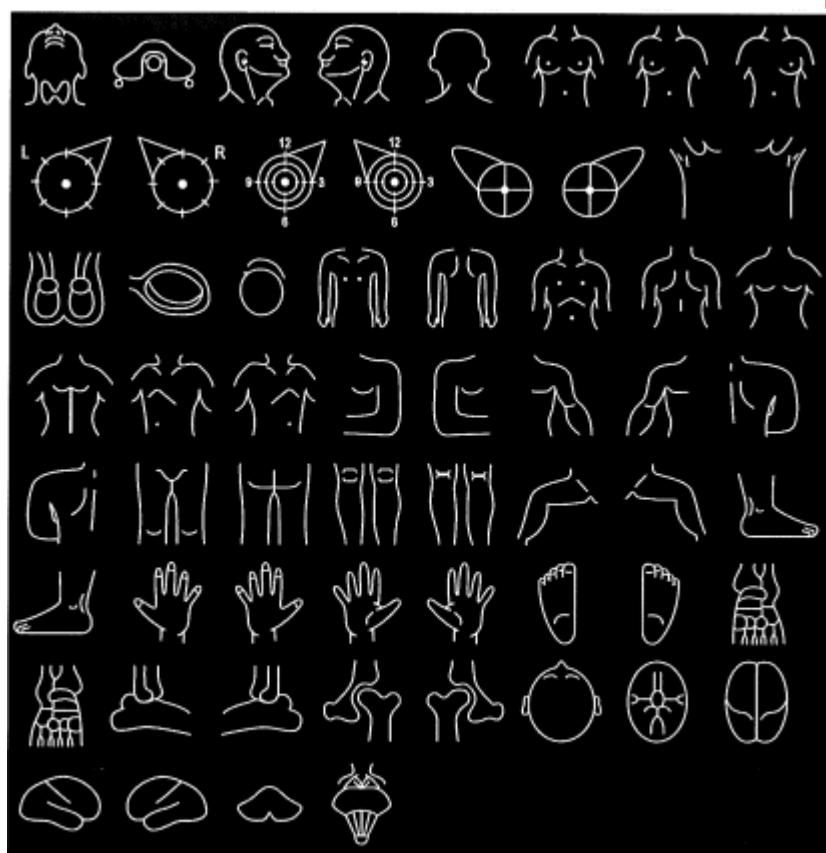
CON

LTD COPY

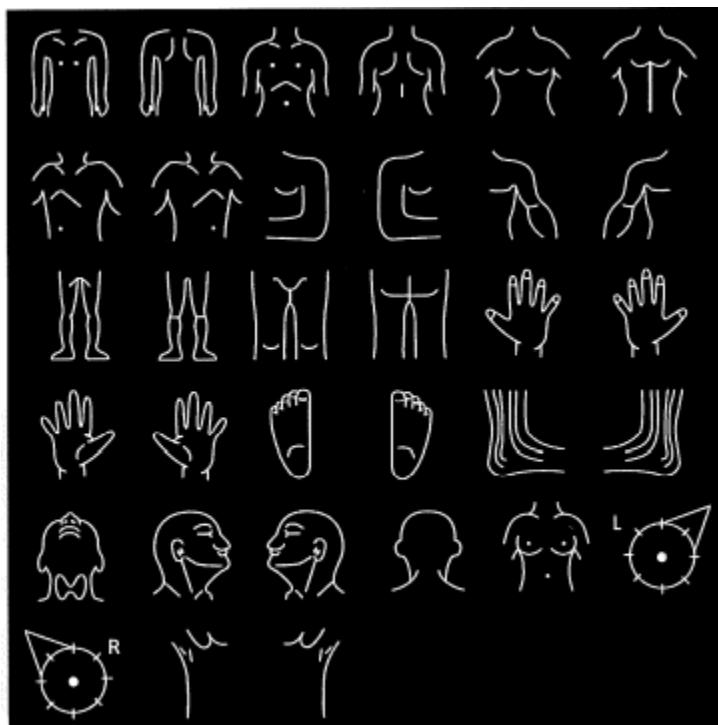


Vascular Mark

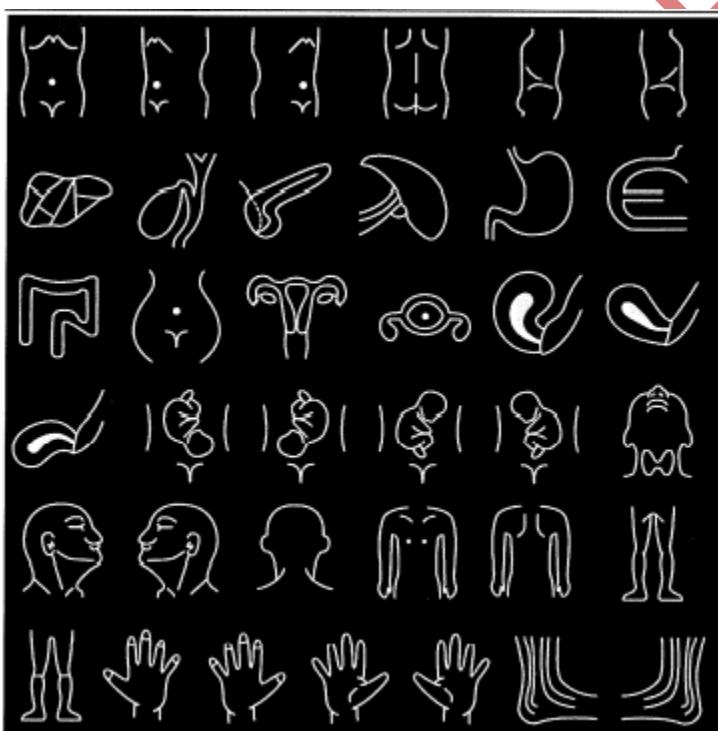
scopy



Small Part Mark



Nerve Mark



Fast Mark

Endoscopy

### 5.12.2 Bodymark Operation

Operation:

1. Press  to enter the state of the body.
2. Select the bodymark you need.
3. Move the trackball after adding the bodymark image, then adjust the probe position. Turn [MENU] or [ANGLE] to adjust the probe direction. Press the ENTER button to confirm when the adjustment is complete.
4. Move trackball to change body mark position;
5. If you want to exit the bodymark function, press  again;
6. Press [EXIT] to exit the body status and the bodymark is displayed on the screen.
7. Press [DEL] to remove the body mark.

### 5.13 Set Arrow Direction

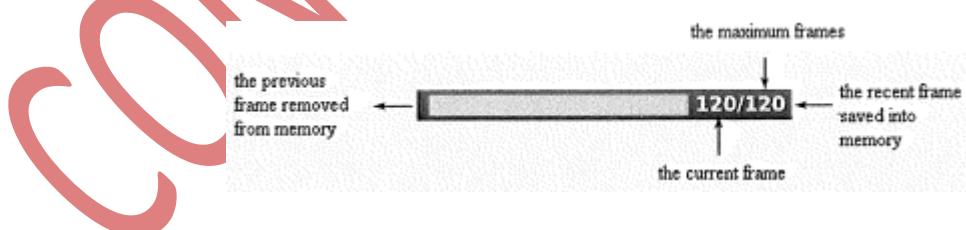
Operation:

1. Press  to display arrows.
2. Press [Change] to select the cursor type; arrow or cross. Change cursor size.
3. Adjust the probe position. Turn [MENU] or [ANGLE] to change the probe direction.
4. Press [ENTER] to confirm when the adjustment is complete.
5. Press [EXIT] to exit arrow settings.
6. Press [DEL] to delete the inputted arrow.

### 5.14 Image and Cine Disposition

#### 5.14.1 Cine Storage Principle

In real-time image status, images can be stored in the movie memory in chronological order, the maximum frame can be set. The maximum number of frames from movie storage can be set, please refer to the presets chapter. If the movie memory is full, the most recent frame is stored in memory, the previous frame is deleted from memory.



Cine Loop Indicator Chart

### 5.14.2 Manual Loop

Press [FREEZE] to stop the image, display the cine playback block, at that time move the cursor to play the cine by hand; the trackball rolls right, the loop rotates the cine with the sequence side by side. Or press [Next/Pre] to play the cine.

### 5.14.3 Automatic Loop

After stopping the image, press [Play/Pause] to play the cine, press again to stop the cine. Press [ENTER] to select the required area of autoplayback.

### 5.14.4 Save and Recall Image

 Press  to save the current image, the image will be displayed on the bottom of the screen; If you want to recall a saved image, move the cursor to the desired image, then press [ENTER] to recall it; or you can recall the patient information file to recall the image, please refer to the Archives chapter.

### 5.14.5 Save and Recall Cine

 In freeze status, press  to save the cine, the cine will be displayed at the bottom of the screen, move the cursor to the required cine, press [ENTER] to redial the cine.

### 5.14.6 Delete Images

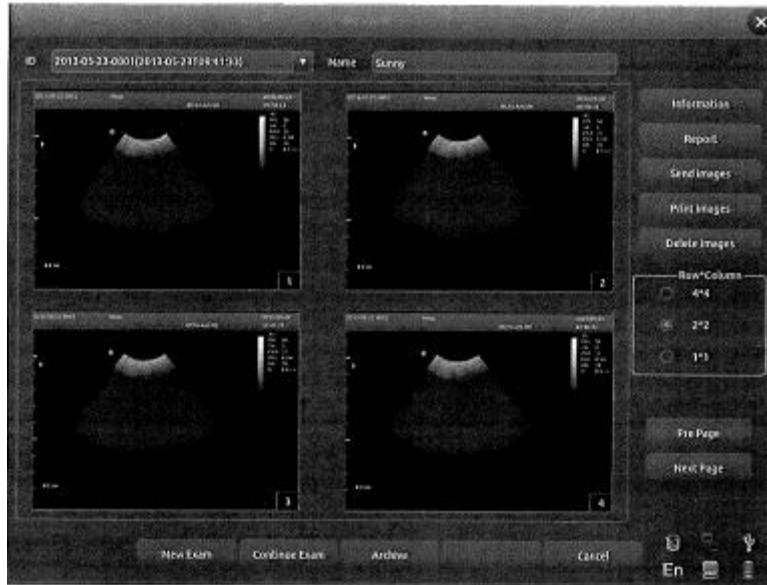
After recalling the image, press [Delete Images] to delete the file.

### 5.14.7 Send Images

After recalling images, press [Send Images] to send images to a USB flash drive, DICOM storage, and printing.

### 5.15 Image Browse

Press  to enter the image browsing information interface. Press [ENTER] on any function in the picture.

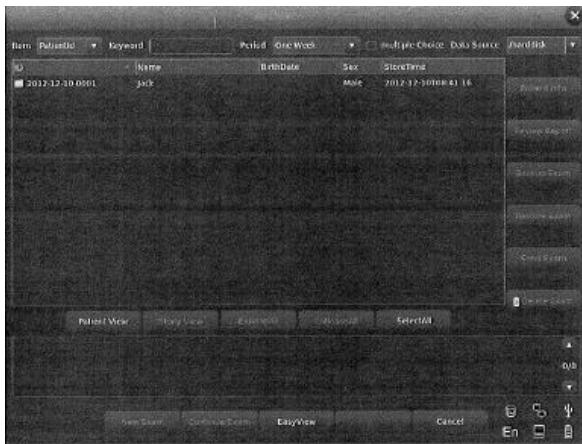


Review Interface

- ID: ID of the current patient;
- Name: current patient's name
- Information: current patient information interface
- Report: current patient report interface
- Send images: send images to USB hard disk, DICOM storage and printing
- Print the Image: prints the selected image, the image will be printed in an array
- Delete the Image: delete the selected image
- Row\*Column: choose the image format
- Pre page: previous page
- Next page: next page
- New exam: exit the current exam and open a new dialog box
- Continue exam: exit the image browsing interface and continue examining the current patient
- Archive: open the archive management interface
- Cancel: turn off the image browsing interface

### 5.16 Archive Management

Records management can search for patient information that has been stored in the system. Press [Archive] to enter the archive management interface, all processes can be opened by moving the cursor.



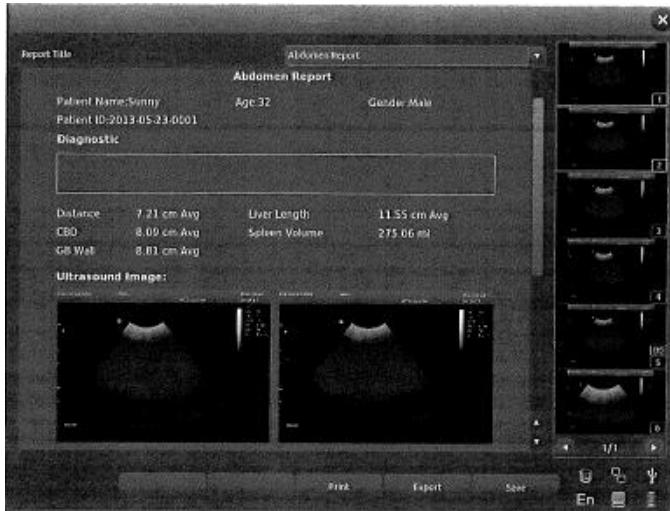
- Item: type selection, select Patient ID or Name;
- Keyword: search for keywords;
- Period: filter time, select today, one week, one month, three months, six months, one year and others;
- Multiple Choice: Multiple choice;
- Data Source: Path selection, select hard disk or U disk;
- Patient Info: enter the patient information interface;
- Review Report: enter the report interface;
- Backup Exam: select examination information to USB hard disk;
- Restore Exam: recover examination information from USB hard disk;
- Send Exam: send selected examination information remotely to USB hard disk or DICOM/Print storage (Need to enable DICOM);
- Delete Exam: delete selected examination information;
- Patient View: change the display mode of the information;
- Expand All: select Patient View, this function will display sub-directories
- Collapse All: exit sub-directories;
- Select All: select all examination information;
- New Exam: exit current patient examination;
- Continue exam: exit the image browsing interface and continue examining the current patient
- Easy View: Exit the archive management interface and open the image browsing interface;
- Cancel: Exit the records management interface and keep the current patient examination;

### 5.17 Report

Press [ENTER] on the image to add the image to the report page. Reports can be saved and printed. This makes it easier for doctors to view and edit patient information.

Reports contain normal reports, abdominal reports, cardiac reports, small organ reports, etc. Move the cursor to the required report page and press [ENTER] to select.

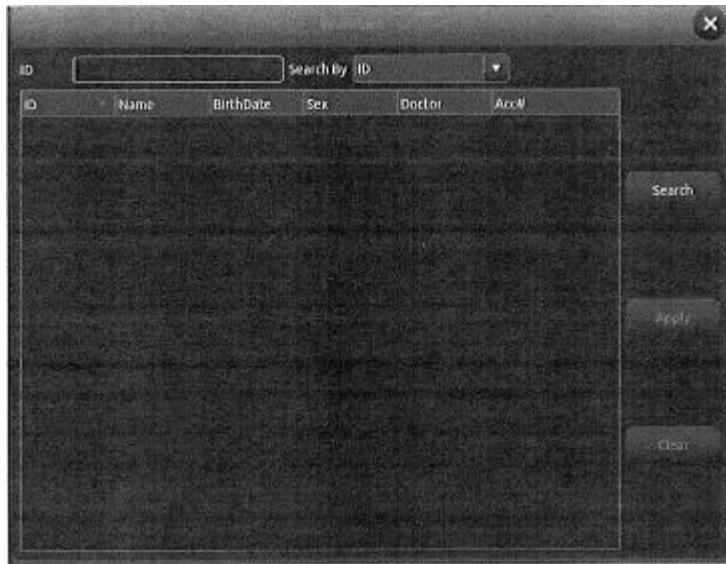
Press [Report] and the page will display the report page of the current exam mode. Change the other exam mode report with the drop-down box.



- Report Title: report selection, various types of reports can be selected, such as Normal, OB/GYN, etc
- Host: displays the name of the hospital.
- Abdomen Report: Displays the report type.
- Patient Name: Displays the patient name.
- Age: Displays the patient's age.
- Sex: Displays the gender of the patient.
- Patient ID: Displays the patient ID.
- Diagnostic: input diagnostic instructions.
- Description: input the description of the symptoms.
- Tips: input note information.
- Send DICOM SR: After enabling DICOM, send DICOM structural report to server
- Print: Prints a report with images.
- Export: Export PDF report to U disk.
- Save: Save the report in the system.
- The image on the right side: Press [ENTER] on the image to add the image to the report.

### 5.18 DICOM

Press [Worklist] on the patient interface, a dialog box will appear as shown below

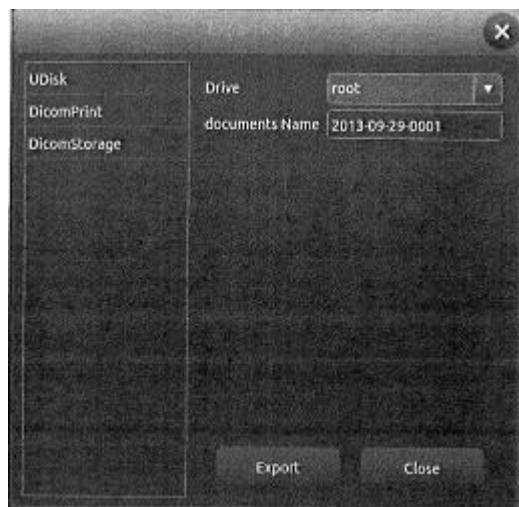


#### 5.18.1 DICOM Worklist

- ID: input ID or some characters, server need fuzzy query;
- Search By: select term, ID or name;
- ID: display the patient ID;
- Name: displays the names of the patients;
- BirthDate: displays the patient's date of birth;
- Sex: displays the gender of the patient;
- Doctor: displays the doctor's name;
- Acc #: displays the number of accessions from the patient;
- Search: press this button to perform a search operation;
- Apply: select the wanted patient and press this button, input all patient information into the new patient interface;
- Clear: deletes all searched content.

### 5.18.2 DICOM Storage

Check "save and send" in settings, then DICOM storage when saving cine and images. Press the submit button in the archive or freeze interface. The DICOM send interface is as follows:



DICOM Send. interface

Select DICOM Storage on the left, select the DICOM server and press the Export to DICOM storage button. Enter Task Sequence and view or edit the DICOM process

### 5.18.3 DICOM Print

DICOM Print operation is the same as DICOM Storage

### 5.18.4 DICOM SR

Press [Send DICOM SR] on the report interface, this task will be entered into the Task Sequence.

## CHAPTER 6 MEASUREMENT AND CALCULATION

The main contents of this chapter are:

Normal measurement and calculation in B mode and M mode, measurement and calculation in OB and Urology fields, etc., the system can enter the appropriate measurement mode depending on the current examination mode, and enter the appropriate report depending on the measurement mode.

The system has a default built-in measurement according to the exam mode, for measurement changes refer to the preset settings chapter.

**⚠ CAUTION:** Choose ultrasound image, measuring instrument and measurement method according to the user's diagnostic needs. The final measurement results must be determined and verified by the doctor. Measurement accuracy is affected by many non-technical factors, such as operator experience, and patient status. Don't just use ultrasound measurement results as the sole basis for the diagnostic process, always use other clinical information to carry out an integrated diagnosis.

### 6.1 Keyboard for Measurement

#### 6.1.1 Trackball

The trackball is used to move the cursor, the main functions of the trackball are as follows:

1. Before starting the measurement, use the trackball to make menu selections.
2. After starting the measurement, move the trackball to move the cursor, during the measurement, the cursor does not have to move in the drawing area.
3. During the Ellipse measurement method, use the trackball to change the short length of the axis.
4. To update the measurement result, move the trackball to change the position of the measurement result.

#### 6.1.2 [ENTER]

During measurement, the [ENTER] function is as follows:

1. When the cursor is in the menu position, press the ENTER button to select the option and start the measurement.
2. During measurement, press the ENTER button to specify the start point and end point of the measurement.

#### 6.1.3 [Update]

1. Before measurement, press [Update] to change the measurement method, such as ellipse, trace. The measurement item changes to "<>".
2. During measurement, [Update] is used to switch to the start point and end point of the measurement, the long axis and the short axis when the measurement has not been completed.
3. During distance measurement, press [ENTER] to fix the starting point, when the end point is not fixed, press [Update] to switch between the starting point and the end point of the measurement.
4. During Ellipse measurement, when will fix the long axis, but the short axis is not fixed, press [Update] to switch between the long and short axes.

#### 6.1.4 [DEL]

The main functions of DEL are as follows:

In frozen state, press [DEL], to delete all measurement results, comments and traces.

**6.1.5 [Change]**

Press **[Change]** to switch to another menu.

**6.1.6 [EXIT]**

Press **[EXIT]** to exit the measurement menu.

**6.1.7 Parameter control button**

Press the appropriate button to update the function and use the function.

**6.2 B Mode General Measurement Method**

Mode B contains Distance, Ellipse, and Trace measurements.

**6.2.2 Meas. Distance**

Measurement Steps:

1. Press the **[Calc]** key to enter the measurement menu. Press the **[distance]** item in the menu or press the **[Dist]** quick measure button; then the "+" icon will be displayed on the measurement screen.
2. Move the "+" icon using the trackball to match one point of the line. Press **[ENTER]** to fix the starting point and the cursor can be moved to the next position.
3. Press **[Update]** to change which point is activated, and position another point on the line accordingly.
4. Move the cursor to the measurement end point, press **[ENTER]** again to complete the measurement.
5. After the measurement is complete, the result will be displayed in the measurement results area.
6. Repeat the steps from point 1 to 4 to start the next distance measurement "". Press **[DEL]** to clear all measurements.

**Notes:**

Each measurement group is limited, if the measurement result exceeds the existing limit, the system will automatically start a new measurement group.

**6.2.3 Ellipse**

Elliptical Measurement Steps:

1. Press the **[Calc]** key to enter the measurement. Press the **[Ellipse]** item in the menu or press the **[Ellipse]** quick measure button; then the system will display the "+" icon segment.
2. Move the "+" icon using the cursor, Press **[ENTER]** to fix the point and the cursor can be moved to a round shape.
3. Press **[Update]** to change the point on and off.
4. Move the cursor to the end-point of the ellipse, press **[ENTER]** to correct the axis, at the same time, the next axis will be updated, and the size of the axis can be changed using the cursor.
5. Press **[Update]** to exit step 4.
6. After fixing the next axis, press **[ENTER]** to complete the measurement.
7. After the measurement, the result will be displayed in the measurement result area.
8. Repeat steps 1 through 6 to start the next "ellipse" measurement. Press **[DEL]** to clear all measurements.

**Notes:**

Each measurement group is limited, if the measurement result exceeds the existing limit, the system will automatically start a new measurement group.

#### 6.2.4 Traces

Measurement steps:

1. Press the [Calc] key to enter the measurement. Update [Trace] item in menu or press quick measure button [Trace]; this will show the "+" icon segment.
2. Move the "+" icon with the cursor, Press [ENTER] to fix the point and the cursor can be moved to the next position.
3. Make the cursor trace along the edge of the examination area, the traced line cannot be closed.
4. Press [Update] to cancel the trace.
5. Press [ENTER] again at the end point, the start point and end point of the trail line will be closed by a straight line.
6. After the measurement, the results will be displayed in the measurement results area.
7. Repeat steps from 1 to 5 to start the next "footprint" measurement. Press [DEL] to clear all measurements.



##### Notes:

Each measurement group is limited, if the measurement results are out of bounds, a new group of measurements will automatically start.

#### 6.2.5 Histogram

The histogram is used to calculate the gray distribution of the ultrasound echo signal within a given area. Use the rectangle, ellipse or trace method to draw along the desired measurement area. The results will be displayed in the form of a histogram.

Histograms can be measured only on freeze images.

- Steps of measurement with the rectangular method:
  1. Press [Calc] to enter measurement, press [Change] to switch measurement menu to [General].
  2. Press [ENTER] on the [Histogram] menu to enter the measurement status.
  3. Press [ENTER] to fix one of the tops of the rectangle.
  4. Move the trackball to change the cursor position and fix the diagonal points of the rectangle
  5. Move the trackball to change the cursor position, fix the diagonal point of the rectangle, and press [ENTER] again to confirm the measurement area. The results will be displayed in the measurement results area.
- Measurement steps with ellipse or trail method: the method used is the same as measuring ellipse or trail, press [Update] to change the measurement between ellipse and trail.

The horizontal axis represents the gray scale of the image from 0 to 255.

The vertical axis represents the distribution ratio of each gray scale. The values displayed at the top of the vertical axis represent the percentage of grays that are maximally distributed in the overall gray distribution.

#### 6.2.6 Cross-sectional chart

The cross-sectional diagram is used to measure the gray distribution of the ultrasound signal in the vertical or horizontal direction in a given profile.

This measurement is only available in freeze mode.

Measurement steps:

1. Press [Calc] to enter measurement, press [Change] to switch measurement menu [General].
  2. Press [ENTER] on the [Profile] menu to enter the measurement status.
  3. Draw a straight line at the measuring position. This method is the same as measuring distance.
  4. The result calculated from the profile will be displayed in the center of the screen.
    - 1 - The horizontal (or vertical) axis represents the projection of the profile line in the horizontal direction.
    - 2 - The vertical (or horizontal) axis represents the gray distribution corresponding to the points on the profile line.
- This range is 0 to 255.

### 6.3 B Fast Measurement

Press [Dist] to enter Quick measurement in B mode. Press the appropriate parameter control button to switch to the quick measurement item.

Measurement Menu	Submenu	Unit	Measurement method/ formula	Comment
Distance	Distance	cm	Refer to distance measurement	
	Ratio (Distance)		Refers to distance measurement. $R = D1/D2$	D1 : First distance D2 : Second distance
	Angle	deg	Refer to distance measurement	Angle Range: 00~1800
Area	Area/circle	Area cm <sup>2</sup> circle cm	Refers to elliptical and trace measurements	Ellipses and traces
Volume	Volume (1 straight line)	ml	Refers to distance measurement. Formula : $V = (\pi/6)xD3$	D means: Depth
	Volume (1 ellipse)	ml	Refers to elliptical measurements. Formula : $V = (\pi/6)xAxB2$	A = Long Axis B = Short Axis
	Volume (2 straight lines)	ml	Refers to distance measurement. Formula : $V = (\pi/6)xD1xD2$	D1 : Longer distance D2 : Shorter distance
	Volume (3 straight lines)	ml	Refers to distance measurement. Formula : $V = (\pi/6)xD1xD2xD3$	D1, D2, D3 : Distance
	Volume (1 Straight Line, 1 Ellipse)	ml	Refers to measuring distances and ellipses. Formula : $V = (\pi/6)xAxBxM$	A = Long Axis B = Short Axis M = Distance

### 6.4 B General Measurement

Press [B], [B/ B] or [4B] to enter into B, B/ B or 4B mode, then press [Calc] to enter measurement status. Or press [Change] to select a common measurement.

Measurement Menu	Submenu	Unit	Measurement method/ formula	Comment
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	Distance	cm	Refer to distance measurement	
	Area/circle	Area cm <sup>2</sup> circle cm	Refers to elliptical and trace measurements	Press [Update] change ellipse and distance
	Volume (1 straight line)	ml	Refers to distance measurement. Formula : $V = (\pi/6)xD^3$	D means: Depth
	Volume (1 ellipse)	ml	Refers to elliptical measurements. Formula : $V = (\pi/6)xAxB^2$	A = Long Axis B = Short Axis
	Volume (2 straight lines)	ml	Refers to distance measurement. Formula : $V = (\pi/6)xD1xD2^2$	D1 : Longer distance D2 : Shorter distance
	Volume (3 straight lines)	ml	Refers to distance measurement. Formula : $V = (\pi/6)xD1xD2xD3$	D1, D2, D3 : Distance
	Volume (1 Straight Line, 1 Ellipse)	ml	Refers to measuring distances and ellipses. Formula : $V = (\pi/6)xAxBxM$	A = Long Axis B = Short Axis M = Distance
Ratio	Ratio (Distance)		Refer to distance measurement Formula $R = D1/ D2$	D1: First distance D2: Second distance
	Ratio (Area)		Refers to elliptical measurements Formula : $R = A1/ A2$	A1: First area A2: Second area
Angle		deg	Refer to distance measurement	Angle range: 0 – 180
Histogram			Refer to the histogram	
Cross-sectional chart			Referring to the cross section	

## 6.5 ABD Measurement

Select the ABD exam mode. Freeze the required image, then Press [Calc] to enter the ABD measurement state. Or press [Change] to select the ABD measurement.

Measurement Menu	Submenu	Unit	Measurement Method/ Formula	Comment
Distance		cm	Refer to distance measurement	
CBD		cm	Refer to distance measurement	
GB wall		cm	Refer to distance measurement	
Liver length		cm	Refer to distance measurement	
Pro Aorta	Height	cm	Refer to distance measurement	
	Width	cm	Refer to distance measurement	
	StD%	%	Refers to distance measurement. Formula: $((D1-D2)/D1) \times 100\%$	D1: Length than Normal D2: Length of Stenosis
	StA%	%	Refers to elliptical measurements. Formula: $((A1-A2)/A1) \times 100\%$	A1: Wide than normal A2: Extent of Stenosis
	Vessel Area	cm <sup>2</sup>	Refers to elliptical and trace measurements	Press [Update] to change the ellipse and trace
	Vessel Distance	cm	Refer to distance measurement	
Mid Aorta	Same as above	Same as above	Same as above	Same as above
Distal Aorta	Same as above	Same as above	Same as above	Same as above
Spleen	Length Height Width Volume	cm cm cm ml	Refers to distance measurement. Formula $V = (\pi/6) \times L \times H \times W$	L: long H: high W: width
Renal Vol. (Rt/Lt)	Length Height Width	cm	Refers to distance measurement.	
Lliac (Rt/ Lt)	Height	cm	Refers to distance measurement.	
	Width	cm	Refers to distance measurement.	
	StD%	%	Refers to distance measurement. Formula: $((D1-D2)/D1) \times 100\%$	D1: Length than Normal D2: Length of Stenosis

	StA%	%	Refers to elliptical measurements. Formula: $((A1-A2)/A1) \times 100\%$	A1: Wide than normal A2: Extent of Stenosis
	Vessel Area	cm <sup>2</sup>	Refers to elliptical and trace measurements	Press [Update] to change the ellipse and trace
	Vessel Distance	cm	Refers to distance measurement. Formula: $((D1-D2)/D1) \times 100\%$	

## 6.6 OB Measurement

Select the OB exam mode. Freeze the required image, then Press [Calc] to enter the OB measurement state. Or press [Change] to select the OB measurement.

Measurement Menu	Submenu	Unit	Measurement Method/ Formula	Comment
Distance		cm	Refer to distance measurement	
GS		cm	Refer to distance measurement	Selectable formulas: CFEF, Campbell, Hadlock, Hansmann, Korean, Merz, Shinozuka
CRL		cm	Refer to distance measurement	Selectable formulas: Hadlock, Hansmann, Korean, Nelson, Osaka, Rempen, Robinson, Shinozuka.
BPD		cm	Refer to distance measurement	Selectable formulas: Besis, CFEF, Campbell, Chitty, Hadlock, Hansmann, Jeanty, Johnsen, Korean, Kurtz Merz, Osaka, Rempen, Sabbagh, Shinozuka
HC		cm	Refers to elliptical and trace measurements	Selectable formulas: CFEF, Campbell, Chitty, Hadlock, Hansmann, Johnsen, Korean, Merz
AC		cm	Refers to elliptical and trace measurements	Selectable formulas: CFEF, Campbell, Hadlock, Hansmann, Korean, Merz, Shinozuka

Fetal Biological	YS	cm	Refers to distance measurement.	
	OFD	cm	Refers to distance measurement.	Selectable formula : Hansmann, Korean
	APPD	cm	Refers to distance measurement.	Formula: Bessis
	TAD	cm	Refer to distance measurement	Formula: CFEF
	TCA	cm	Refers to distance measurement.	Formula : Osaka
	FL	cm	Refers to distance measurement.	Selectable formulas: Bessis, CFEF, Campell, Chitty, Doubilet, Hadlock, Hansmann, Hohler, Jeanty, Johnson, Korean, Merz, Osaka, Shinozuka
	Spine Long	cm	Refers to distance measurement.	
	PPE	cm	Refers to distance measurement.	Formula: Hansmann
	TTD	cm	Refers to distance measurement.	Formula: Hansmann
	TC	cm	Refers to distance measurement.	
Fetal Long Bones	HL	cm	Refers to distance measurement.	Selectable formulas: Jeanty, Korean, Merz, Osaka
	Ulna Long	cm	Refers to distance measurement.	Formula : Jeanty
	Tibia Long	cm	Refers to distance measurement.	Selectable formulas : Jeanty, Merz
	Long Radius	cm	Refers to distance measurement.	
	long fibula	cm	Refers to distance measurement.	
Fetal Cranium	Clavicle Long	cm	Refers to distance measurement.	Formula: Yarkoni
	Cerebellum	cm	Refers to distance measurement.	Selectable formulas :Chitty, Hill
	Posterior Cistern	cm	Refers to distance measurement.	
	NF	cm	Refers to distance measurement.	

	NB	cm	Refers to distance measurement.	
	OOD	cm	Refers to distance measurement.	Formula: OOD
	IOD	cm	Refers to distance measurement.	
	NB	cm	Refers to distance measurement.	
	Paracele	cm	Refers to distance measurement.	Formula : Tokyo
	HC Width	cm	Refers to distance measurement.	
OB Others	LtRenal	cm	Refers to distance measurement.	
	RtRenal	cm	Refers to distance measurement.	
	LtRenalAP	cm	Refers to distance measurement.	
	RtRenalAP	cm	Refers to distance measurement.	
	LVWrIIM	cm	Refers to distance measurement.	
	TAD	cm	Refers to distance measurement.	
EFBW		g	Refers to measuring distances and ellipses	Modify formula automatically according to EFBW formula in settings
AFI		cm	Refers to distance measurement.	$AFI = AFI1 + AFI2 + AFI3 + AFI4$
FBP		cm	Refers to distance measurement.	
Cervical Length		cm	Refers to distance measurement.	

### 6.6.1 Twin measurement

1. On the new patient OB page, select the number of pregnancies from one to four.
2. In the measurement menu, press baby A, then press [ENTER] to switch babies, which can measure babies separately.

### 6.6.2 EDD (Estimated Date Delivery)

#### 6.6.2.1 Calculating EDD with LMP (Last Menstrual Period)

- 1.In the new patient OB page, update the LMP input box.
- 2.Select LMP from the date dialog box or enter LMP date directly.
- 3.The calculated EDD value will appear in the results measurement area of the OB page.

#### 6.6.2.2 Calculating EDD with BBT (Basal Body Temperature)

1. On the new patient OB page, update the ovulation date input box and enter the BBT date.
2. This method is the same as the LMP method.

### 6.6.3 Growth curve

Function: Growth curve comparison is used to compare the measured data of the fetus with the normal growth curve to assess whether the fetus is growing normally.

Measurement steps:

1. Complete the measurement of the OB item and go to the report page.
2. Select the growth curve in the list on the right and press [ENTER] to display the growth curve.
3. Select the growth curve that needs to be displayed, and tick to show the growth curve on the report.
4. Press the [X] icon in the dialog box to exit.

 TIP: The abscissa of the growth curve is the gestational week calculated according to the LMP in the patient information.

## 6.7 Pediatric Measurement

Select OB mode, press [Calc] to enter OB mode, then enter pediatric mode. Or press [Change] to switch to the pediatric measurement menu.

### 6.7.1 HIP angle

The HIP function is used to evaluate fetal hip growth. To make calculations, three lines need to be added to the drawing, to match the anatomical structure of the fetus. The system will calculate and display two angles for doctor's reference.

Measurement steps:

1. Select the menu item [HIPAngle], and click to enter the measurement.
2. Click on the line drawing area, and a line with "+" will appear. Move the line to the target measurement area.
3. Rotate [MENU] key to adjust line angle, press [ENTER] key to correct line.
4. Then a second line will appear, adjust the line like step 3, and fix the line.
5. Fix 3 lines, the measurement result of the corner will appear in the district.

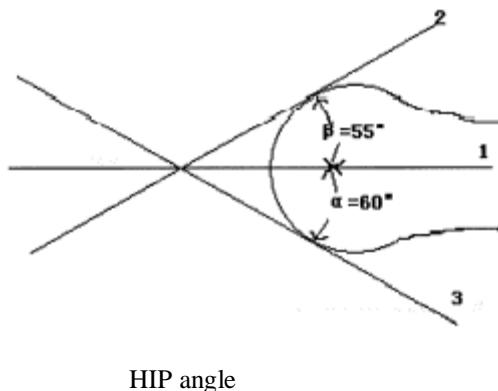
 CAUTION:

D3 shows the line of refraction between the connecting and acetabular bony prominences

D2 shows the direct line between the ossicular and acetabular bones

D 1 shows the baseline between the cotyle, purse joint, cartilaginous periosteum and ilium.

is the angle between D1 and D2 (an acute angle); is the angle between D1 and D3 (an acute angle).



## 6.8 GYN Measurement

GYN measurements include measurements of UT-D (uterine diameter), ENDO (endometrium), CX-L (length of the uterine cervix), LEFT OV and RIGHT OV (left and right ovarian volume) and LEFT FO and RIGHT FO (left and right pouches). The results will be calculated and displayed automatically on the screen by measuring the relevant parameters. Freeze the required image under the GYN exam, then press [Calc] to enter the GYN measurement state.

Measurement Menu	Submenu	Unit	Measurement Method	Comment
Distance		cm	Refers to distance measurement.	
UT	UT_L	cm	Refers to distance measurement.	
	CX_L	cm	Refers to distance measurement.	
	UT_W	cm	Refers to distance measurement.	
	UT_H	cm	Refers to distance measurement.	
Cervix Volume		ml	Refers to distance measurement. Formula: $V = (\pi/6)xLxHxW$	L: Cervix_L H: Cervix_H W: Cervix_W
ENDO		cm	Refers to distance measurement.	
OV Volume (L/R)		ml	Refers to distance measurement. Formula: $V = (\pi/6)xLxHxW$	L: OV_L H: OV_H W: OV_W
FO (L/R)	Follicle width	cm	Refers to distance measurement.	
	Follicle height	cm	Refers to distance measurement.	
	Follicle volume	ml	The formula of 2 distances $V = (\pi/6)xAxB^2$ The formula of 3 distances $V = (\pi/6)xLxHxW$	2 distance A: longer distance B: shorter distance 3 distance L: follicle length H: follicle height W: follicle width

### 6.9 Small Part Measurement

Freeze the required image under small organ examination, then press [Calc] to enter into small organ examination status.

Measurement menu	Submenu	Unit	Measurement method/ formula	Comment
Distance		cm	Refers to distance measurement.	
Thyroid (L/R)	Volume	ml	Refers to distance measurement. Formula: $V = (\pi/6)xLxHxW$	L: Thyroid_L H: Thyroid_H W: Thyroid_W
Angle		deg	Refers to distance measurement.	Angle range 0 – 180
Ratio			Refers to distance measurement. Formula: $R = D1/D2$	D1: first distance D2: second distance

### 6.10 B Mode Vessel Measurement

Refers to normal measurement in mode B.

### 6.11 Urological Measurement

Usually urological measurements are performed in B and B/B modes.

Freeze desired image under urological examination, then press [Calc] to enter in urological measurement status

Measurement menu	Submenu	Unit	Measurement method/ formula	Comment
Kidney Volume (L/R)		cm	Refers to distance measurement. Formula: $V = (\pi/6)xLxHxW$	L: Kidney_L H: Kidney_H W: Kidney_W
Bladder Volume	Volume	ml	Refers to distance measurement. Formula: $V = (\pi/6)xLxHxW$	L: Blader_L H: Blader_H W: Blader_W
Prostate	Volume	deg	Refers to distance measurement. Formula: $V = (\pi/6)xLxHxW$	L: Prostate_L H: Prostate_H W: Prostate_W
	PPSA	ng/ ml	Formula: $PPSA = 0.12xV$	
	PSAD	ng/ ml	Formula: $PSAD = SPSA/V$	SPSA: enter SPSA when creating new patient
RVU	Volume	ml	Refers to distance measurement. Formula: $V = (\pi/6)xLxHxW$	L: RVU_L H: RVU_H W: RVU_W

## 6.12 Cardiac Measurement

*Freeze* desired image under cardiac examination, then press [Calc] to enter the heart measurement status.

Measurement menu	Submenu	Unit	Measurement method/ formula	Comment
Distance		cm	Refers to distance measurement.	
Single Plane		ml	Refers to distance measurement. Formula: $V = (\pi/6)xLxD^2$	Left ventricular parameters at end of diastole: LV long axis SL; LV short axis SD; Left ventricular parameters at the end of systole: LV long axis DL; LV short axis DD;
Bi-Plane		ml	Refer to distance measurement, ellipse measurement. Formula: $V = (8/3)xAm \times Ai / (\pi D)$	D: LV short axis Am: LV area at mitral valve image level Ai: LV area at apex image level
Bullet Volume		ml	Refer to distance measurement, ellipse measurement. Formula: $V = (5/6)xAm \times L$	Am: LV area on the short axis image of the mitral valve L: LV long axis
Modi_Simpson		ml	Refer to distance measurement, ellipse measurement. Formula: $V = (Am + 5 \times Ap / 18) \times L$	Am: LV area on the short axis image of the mitral valve Ap: LV cross-section on papillary muscle level images L: LV long axis
RVU	Volume	ml	Refers to distance measurement. Formula: $V = (\pi/6)xLxHxW$	L: RVU_L H: RVU_H W: RVU_W

## 6.13 Normal measurement in M, B/ M mode

In real-time state, press [B/ M] twice to enter M mode, press [Calc] to enter into M mode measurement state. Or In real-time state, press [B/ M] to enter M mode B/ M, press [Calc] to enter the measurement state of M mode.

### 6.13.1 Distance

Measurement Steps:

1. Select the [Distance] menu item to enter the measurement.
2. Click on the image area M, it will appear a blue dotted line with two short horizontal lines. The blue dotted line represents the position that needs to be measured. The distance between two short lines is the distance you want to measure. The yellow short line represents the line in the active state. Click and drag the short line wherever you want to place it.
3. Press [Update] to activate two short lines in turn and drag them to change the distance between the two lines. The measurement results will be displayed in the results area.

### 6.13.2 Time

LMeasurement steps:

1. Select the menu item [Time] to enter the measurement.
2. Click on the image area M, it will appear a blue dotted line with two short horizontal lines. The blue dotted line represents the position that needs to be measured. The distance between two short lines is the distance you want to measure. The yellow short line represents the line in the active state. Click and drag the short line wherever you want to place it.
3. Press [Update] to activate two short lines in turn and drag them to change the distance between the two lines. The measurement results will be displayed in the results area.

### 6.13.3 Heart rate

Heart rate is used to calculate the number of heart beats per minute from a heart image.

Measurement steps:

1. Select the menu item [Heart Rate] to enter the measurement.
2. method is the same as Time.
3. After the above measurements, the calculated heart rate result is displayed in the measurement results area.
4. Repeat steps from 1 to 3 to start the next measurement.

### 6.13.4 Velocity

Measurement steps:

1. Click [Velocity] to enter the measurement state.
2. Select the starting point and press [ENTER], the start point and cursor are displayed, drag the cursor to the end point.
3. Press [ENTER] again, the measurement is complete, the result will be displayed in the measurement area
4. Repeat 1 – 3, and enter the next speed measurement.



**NOTE:** The maximum number of measurement results in the image area is one. The results of the second measurement will include the first. The area of the measurement result will display all the measurement values.

## 6.14 General Measurements in M mode

In real-time status, press [B/ M] button twice to enter M mode, press [Calc] to enter cardiology M mode measurement status

Measurement menu	Submenu	Unit	Measurement method/ formula	Comment
Distance		cm	Refer to distance measurement M	
time		s	Refers to the time measurement M	
Velocity		cm/s	Refer to the speed measurement M	
HR	One cycle	bpm	Refer to HR M . measurement	
	Double cycle	bpm	Refer to HR M . measurement	

**6.15 M Abdomen Measurement**

Refer to the general measurement mode M

**6.16 M OB Measurement**

Refer to the general measurement mode M

**6.17 M GYN Measurement**

Refer to the general measurement mode M

**6.18 M Mode Cardiac Measurement**

Usually urological measurements are performed in M and B/M modes.

Freeze required image under Urology examination, then press [Calc] to enter Urology measurement status. Or press [Change] to select the heart measurement.

Measurement menu	Submenu	Unit	Measurement method/formula	Comment
Distance		cm	Refer to distance measurement M	
ET		s	Refers to the time measurement M	
HR	One cycle	bpm	Refer to the speed measurement M	
	Double cycle	bpm	Refer to the speed measurement M	
LVMM	IVSd	cm	Refer to distance measurement M	Interventricular Septum
	LVIDd	cm	Refer to distance measurement M	Left ventricular diameter in diastole
	LVIDs	cm	Refer to distance measurement M	Left ventricular diameter in systole
	LVPWd	cm	Refer to distance measurement M	Posterior wall of left ventricle in diastole
	IVSs	cm	Refer to distance measurement M	Interventricular Septal Thickness in Systole
	LVPWs	cm	Refer to distance measurement M	Posterior wall of left ventricle in systole
	EDV	ml	$EDV = 7.0 / (2.4 + LVIDd) \times LVIDd^3$	Left Ventricular Volume at End of Diastole
	ESV	ml	$ESV = 7.0 / (2.4 + LVIDs) \times LVIDs^3$	Left ventricular volume at the end of systole
	SV	ml	$SV =  EDV - ESV $	Motion Volume
	SI		$SI = SV / BSA$	Motion Volume, BSA: Body Surface Area, calculated by entering height and weight
	EF	%	$EF = SV / EDV \times 100$	Ejection fraction
	FS	%	$FS = (LVIDd - LVIDs) / LVIDd \times 100$	contraction fraction
	CO	L/min	$CO = SV \times HR / 1000$	Cardiac output
	CI		$CI = CO / BSA$	ECG Index, BSA: Body Surface Area, calculated by entering height and weight

	LVMW		$LVMW = 1.04 \times [(IVSd + LVIDd + LVPWd)3 - LVIDd3] - 13.6$	
	LVMWI		$LVMWI = LVMW / BSA$	BSA: Body Surface Area, calculated by entering height and weight
	MVCF		$MVCF = (LVIDd - LVIDs) / (LVIDd \times LVET)$	Average reduction of length
Mitral Valve	EF velocity	cm/s	Refer to HR M . measurement	
	AC velocity	cm/s	Refer to HR M . measurement	
	A peak/ E peak		Refer to distance measurement M	
	Mitral Orifice Flow		Refer to HR M and time measurements $QMV = 4 \times DEV \times DCT$	DEV: Mitral Valve Opening Speed DCT: Mitral Valve Opening Time
Aorta	LAD/ AOD		Refer to distance measurement M	LV and aortic diametric ratio
	Aortic Valvular Orifice Flow		$AVSV = (MAVO1 + MAVO2) \times LVET \times 50 + AA$	MAVO1: Distance of the aortic opening at baseline MAVO2: Distance from the aortic opening at the end of AA: Aortic Wall Range of Motion

**6.19 M Urology Measurements**

Refers to common measurements in M mode.

**6.20 M Small Part Measurement**

Refers to common measurements in M mode.

**6.21 M Pediatric Measurement**

Refers to common measurements in M mode.

**6.22 PW mode measurement method**

Press [PW] to enter PW mode, then press [Calc] to enter PW mode measurement.

 **NOTES:**

- To get accurate results, PW images must be clear and of high quality.
- Make sure you place the cursor in the right place on the systole and diastole of the heart

**6.22.1 Velocity**

Refers to the general speed measurement of mode M.

**6.22.2 Time**

Refers to the general measurement of M mode time.

**6.22.3 HR**

Refers to the general HR measurement mode M.

**6.22.4 Auto Trace**

Measurement steps:

1. Move the trackball to select the starting point of a cycle and press [ENTER] to place the cursor.
2. The second cursor "^\" will appear, move the trackball to the end of the cycle, press [ENTER] to place.
3. The measurement results will be displayed on the monitor and calculate other values of the parameters.

**6.22.5 Manual Trace**

Measurement steps:

1. Move the trackball to select the starting point of a cycle and press [ENTER] to place the cursor.
2. Move the trackball along the spectrum and press [ENTER] to finish.
3. The measurement results will be displayed on the monitor and calculate other values of the parameters.

**6.23 PW Fast Measurement**

Press [Dist] to enter PW fast metering in PW mode. Press the appropriate control parameter button to switch to the quick measurement item.

Measurement menu	Submenu	Unit	Measurement method/ formula	Comment
Peak	vs	cm/s	Refer to the speed measurement M	
	Pressure(s)	mmHg	Formula: Pressure = 4 x Vs x Vs/10000	
	Vd	cm/s	Refer to the speed measurement M	
	Pressure (d)	mmHg	Formula: Pressure = 4 x Vd x Vd/10000	
	SD		Formula: SD = Vs/ Vd	
	RI		Formula: RI = (Vs - Vd)/ Vs	
HR	time	s	Refers to the time measurement M	
	Single wave	bpm	Refer to HR M . measurement	
Auto Trace/ Manual Trace	vs	cm/s	Refer to the speed measurement M	
	Pressure(s)	mmHg	Formula: Pressure = 4 x Vs x Vs/10000	
	Vd	cm/s	Refer to the speed measurement M	
	Pressure (d)	mmHg	Formula: Pressure = 4 x Vd x Vd/10000	

	Vmean	cm/s	Refer to the speed measurement M	
	Pressure (VMean)	mmHg	Formula: Pressure = 4 x VMean x VMean/10000	
	TVI	cm		
	SD		Formula: SD = Vs/ Vd	
	RI		Formula: RI = (Vs - Vd)/ Vs	
	PI		Formula: PI = (Vs - Vd)/ VMean	
	HR (single wave)	bpm		

#### 6.24 PW General Measurement

Press [Calc] to enter PW measurement in PW mode. Press the appropriate parameter control button to switch to common measurement items.

Measurement menu	Submenu	Unit	Measurement method/ formula	Comment
Velocity		cm/s	Refer to the speed measurement M	
Distance		cm	Refer to distance measurement M	
Peak	vs	cm/s	Refer to the speed measurement M	
	Pressure(s)	mmHg	Formula: Pressure = 4 x Vs x Vs/10000	
	Vd	cm/s	Refer to the speed measurement M	
	Pressure (d)	mmHg	Formula: Pressure = 4 x Vd x Vd/10000	
	SD		Formula: SD = Vs/ Vd	
	RI		Formula: RI = (Vs - Vd)/ Vs	
	time	s	Refers to the time measurement M	
Auto Trace/ Manual Trace	vs	cm/s	Refer to the speed measurement M	
	Pressure(s)	mmHg	Formula: Pressure = 4 x Vs x Vs/10000	
	Vd	cm/s	Refer to the speed measurement M	
	Pressure (d)	mmHg	Formula: Pressure = 4 x Vd x Vd/10000	
	Vmean	cm/s	Refer to the speed measurement M	

	Pressure (VMean)	mmHg	Formula: Pressure = 4 x VMean x VMean/10000	
	TVI	cm		
	SD		Formula: SD = Vs/ Vd	
	RI		Formula: RI = (Vs - Vd)/ Vs	
	PI		Formula: PI = (Vs - Vd)/ VMean	
	HR (single wave)	bpm		
StD%	Distance1	cm	Refers to distance measurement B	
	Distance2	cm	Refers to distance measurement B	
	std%	%	Formula: StD% = ((D1-D2) / D1) x 100%	D1: Distance 1 D2: Distance 2
StA%	Area1	cm <sup>2</sup>	Refers to the measurement of the ellipse B	
	area2	cm <sup>2</sup>	Refers to the measurement of the ellipse B	
	STA%	%	Formula: StD% = ((A1-A2) / A1) x 100%	A1: Area 1 A2: Area 2
ICA/ CCA	ICA	cm/s	Refer to the speed measurement M	
	Pressure (ICA)	mmHg	Formula: Pressure = 4 x ICA x ICA/10000	
	CCA	cm/s	Refer to the speed measurement M	
	Pressure (CCA)	mmHg	Formula: Pressure = 4 x CCA x CCA/10000	
	ICA/ CCA		Formula: ICA/ CCA	
Flow Volume	Diameter	cm	Refers to distance measurement B	
	TVI	cm		
	time	s	Refers to the time measurement M	
	HR (Single wave)	bpm		
	SV	ml	Formula: 0.785 * Diameter * Diameter *  TV1	
	CO	L/min	Formula: SV * HR (Single wave)/ 1000	

**6.25 PW Abdomen Measurement**

Refer to the general measurement of PW.

**6.26 OB PW Measurement**

Press [Calc] to enter PW measurement in OB PW mode. Or press the corresponding parameter control button to switch to the OB measurement item.

<b>Measurement menu</b>	<b>Submenu</b>	<b>Unit</b>	<b>Measurement method/ formula</b>	<b>Comment</b>
Umb A	vs	cm/s	Refer to the speed measurement M	
	Pressure(s)	mmHg	Formula: Pressure = 4 x Vs x Vs/10000	
	Vd	cm/s	Refer to the speed measurement M	
	Pressure (d)	mmHg	Formula: Pressure = 4 x Vd x Vd/10000	
	Vmean	cm/s	Refer to the speed measurement M	
	Pressure (VMean)	mmHg	Formula: Pressure = 4 x VMean x VMean/10000	
	TVI	cm		
	SD		Formula: SD = Vs/ Vd	
	RI		Formula: RI = (Vs - Vd)/ Vs	
	PI		Formula: PI = (Vs - Vd)/ VMean	
	HR (Single wave)	bpm		

**6.27 PW GYN Measurement**

Press [Calc] to enter PW measurement in GYN PW mode. Or press the appropriate parameter control button to switch to the GYN measurement item.

<b>Measurement menu</b>	<b>Submenu</b>	<b>Unit</b>	<b>Measurement method/ formula</b>	<b>Comment</b>
Umb A	vs	cm/s	Refer to the speed measurement M	
	Pressure(s)	mmHg	Formula: Pressure = 4 x Vs x Vs/10000	
	Vd	cm/s	Refer to the speed measurement M	
	Pressure (d)	mmHg	Formula: Pressure = 4 x Vd x Vd/10000	
	Vmean	cm/s	Refer to the speed measurement M	
	Pressure (VMean)	mmHg	Formula: Pressure = 4 x VMean	

		x VMean/10000	
TVI	cm		
SD		Formula: SD = Vs/ Vd	
RI		Formula: RI = (Vs - Vd)/ Vs	
PI		Formula: PI = (Vs - Vd)/ VMean	
HR (Single wave)	bpm		

### 6.28 PW Cardiology Measurements

Press [Calc] to enter PW measurement in PW cardiology mode. Or press the appropriate parameter control button to switch to the cardiology measurement item.

Measurement menu	Submenu	Unit	Measurement method/ formula	Comment
LVOT	Peak Velocity	cm/s	Refer to the speed measurement M	
	Peak Pressure	mmHg	Formula: Pressure = 4 x Peak Velocity x Peak Velocity/10000	
	Diameter	cm	Refers to distance measurement B	
	Area Diameter	cm <sup>2</sup>	Formula: * Diameter * Diameter / 4	
	vs	cm/s	Refer to the speed measurement M	
	PPG	mmHg	Formula: PPG = 4 x Vs x Vs/10000	
	Vmean	cm/s	Refer to the speed measurement M	
	MPG	mmHg	Formula: MPG = 4 x VMean x VMean/10000	
	TVI	cm		
	time	s	Refers to the time measurement M	
	HR (single wave)	bpm		
	SV	ml	Formula: 0.785 * Diameter * Diameter *  TV1	
	CO	L/min	Formula: SV * HR (Single wave)/ 1000	
AV	Diameter	cm	Refers to distance measurement B	
	Area	cm <sup>2</sup>	Refer to B . trace measurement	
	ACC	cm/s <sup>2</sup>	Refer to the speed measurement M	

	AV Trace Vs	cm/s	Refer to the speed measurement M	
	AV Trace PPG	mmHg	Formula: $PPG = 4 \times Vs \times Vs/10000$	
	Av Trace VMean	cm/s	Refer to the speed measurement M	
	AV Trace MPG	mmHg	Formula: $Pressure = 4 \times VMean \times VMean/10000$	
	AV Vmax Velocity	cm/s	Refer to the speed measurement M	
	AV Vmax Pressure	mmHg	Formula: $Pressure = 4 \times Velocity \times Velocity/10000$	
	AV IPM Peak	cm/s	Refer to the speed measurement M	
	AV IPM Pressure	mmHg	Formula: $Pressure = 4 \times VPeak \times VPeak/10000$	
	AV IPM Slope	cm/s <sup>2</sup>		
	AV IPM	s		
	AV IPM Area	cm <sup>2</sup>		
	R – R interval	bpm		
	AR Trace Vs	cm/s	Refer to the speed measurement M	
	AR Trace PPG	mmHg	Formula: $PPG = 4 \times Vs \times Vs/10000$	
	AR Trace VMean	cm/s	Refer to the speed measurement M	
	AR Trace MPG	mmHg	Formula: $Pressure = 4 \times VMean \times VMean/10000$	
	AR Vmax Velocity	cm/s	Refer to the speed measurement M	
	AR Vmax Pressure	mmHg	Formula: $Pressure = 4 \times Velocity \times Velocity/10000$	
	AR IPM Peak	cm/s	Refer to the speed measurement M	
	AR IPM Pressure	mmHg	Formula: $Pressure = 4 \times VPeak \times VPeak/10000$	
	AR IPM Slope	cm/s <sup>2</sup>		
	AR IPM	s		
	AR IPM Area	cm <sup>2</sup>	Formula: 220/ AV IPM	
MV	ePeak	cm/s	Refer to the speed measurement M	
	EPeak Pressure	mmHg	Formula: $Pressure = 4 \times EPeak \times EPeak/10000$	

	APeak	cm/s	Refer to the speed measurement M	
	APeak Pressure	mmHg	Formula: Pressure = 4 x APeak x APeak/10000	
	E/ A	%	Formula: EPeak/ APeak * 100	
	MV VPeak	cm/s	Refer to the speed measurement M	
	MV IPM Pressure	mmHg	Formula: Pressure = 4 x VPeak x VPeak/10000	
	MV IPM Slope	cm/s <sup>2</sup>		
	MV IPM	s		
	MV IPM Area	cm <sup>2</sup>	Formula: 220/ MV IPM	
	E Duration	s	Refers to the time measurement M	
	A Duration	s	Refers to the time measurement M	
	IRT	s	Refers to the time measurement M	
	MV Diameter	cm	Refers to distance measurement B	
	MV Area	cm <sup>2</sup>	Refer to B . trace measurement	
	MV Trace Vs	cm/s	Refer to the speed measurement M	
	MV Trace PPG	mmHg	Formula: PPG = 4 x Vs x Vs/10000	
	MV Trace Vmean	cm/s	Refer to the speed measurement M	
	MV Trace MPG	mmHg	Formula: MPG = 4 x VMean x VMean/10000	
	MV Trace TVI	cm		
	time	s	Refers to the time measurement M	
	MV Trace HR	bpm	Formula: 60/ Time	
	MV Trace SV	ml	Formula: 0.785 * Diameter * Diameter *  TV1	
	MV Trace CO	L/min	Formula: SV * HR (Single wave)/ 1000	
	R – R interval	bpm		
	MR Vmax	cm/s	Refer to the speed measurement M	
	MR Vmax Pressure	mmHg	Formula: Pressure = 4 x Vmax x Vmax/10000	
	MR TVI	cm		

TV	TV Manual Trace Vs	cm/s	Refer to the speed measurement M	
	TV Manual Trace PPG	mmHg	Formula: PPG = 4 x Vs x Vs/10000	
	TV Manual Trace Vmean	cm/s	Refer to the speed measurement M	
	TV Manual Trace MPG	mmHg	Formula: MPG = 4 x VMean x VMean/10000	
	TV Manual Trace TVI	cm		
	VPeak IPM TV	cm/s	Refer to the speed measurement M	
	IPM Pressure TV	mmHg	Formula: Pressure = 4 x VPeak x VPeak/10000	
	TV IPM Slope	cm/s <sup>2</sup>		
	IPM TV	s		
	TV IPM Area	cm <sup>2</sup>	Formula: 220/ IPM TV	
	R – R interval	bpm		
	TR Manual Trace Vs	cm/s	Refer to the speed measurement M	
	TR Manual Trace PPG	mmHg	Formula: PPG = 4 x Vs x Vs/10000	
	TR Manual Trace Vmean	cm/s	Refer to the speed measurement M	
	TR Manual Trace MPG	mmHg	Formula: MPG = 4 x VMean x VMean/10000	
	TR Manual Trace TVI	cm		
	TR Vmax	cm/s	Refer to the speed measurement M	
	TR Vmax Pressure	mmHg	Formula: Pressure = 4 x Vmax x Vmax/10000	
	TR TVI	cm		
PV	InFlow Velocity	cm/s	Refer to the speed measurement M	
	InFlow Pressure	mmHg	Formula: Pressure = 4 x Velocity x Velocity/10000	
	PV Diameter	cm	Refers to distance measurement B	
	PV Trace Vs	cm/s	Refer to the speed measurement M	
	PV Trace PPG	mmHg	Formula: PPG = 4 x Vs x Vs/10000	
	PV Trace Vmean	cm/s	Refer to the speed measurement M	

Pul. Vein	PV Trace MPG	mmHg	Formula: MPG = 4 x VMean x VMean/10000	
	PV Trace TVI	cm		
	time	s		
	PV Trace HR	bpm	Formula: 60/ Time	
	PV Trace SV	ml	Formula: 0.785 * Diameter * Diameter *  TV1	
	PV Trace CO	L/min	Formula: SV * HR (Single wave)/ 1000	
	RV ET	s	Refers to the time measurement M	
	RV AcT	s	Refers to the time measurement M	
	RV AcT/ ET		Formula: AcT/ ET	
	RV REP	s	Refers to the time measurement M	
	RV STI		Formula: REP/ ET	
	PV IPM VPeak	cm/s	Refer to the speed measurement M	
	PV IPM Pressure	mmHg	Formula: Pressure = 4 x VPeak x VPeak/10000	
	PV IPM Slope	cm/s <sup>2</sup>		
	PV IPM	s		
	PV IPM Area	cm <sup>2</sup>	Formula: 220/ IPM TV	
	R – R interval	bpm		
	PR Vmax	cm/s	Refer to the speed measurement M	
	PR Vmax Pressure	mmHg	Formula: Pressure = 4 x Vmax x Vmax/10000	
	Pul. Vein vs	cm/s	Refer to the speed measurement M	
	Pul. Vein Vd	cm/s	Refer to the speed measurement M	
	Pul. SD Veins		Formula: SD = Vs/ Vd	
	ARV	cm/s	Refer to the speed measurement M	
	ARD	s	Refers to the time measurement M	

**6.29 PW Vascular Measurement**

Press [Calc] to enter the measurement in PW vascular mode. Or press the appropriate parameter setting button to switch to the vascular measurement item.

Measurement menu	Sub Menu	Unit	Measurement Method/Measurement Formula	Comment
Subclav	vs	cm/s	Refer to the speed measurement M	
	Pressure (Vs)	mmHg	Formula: $Tekanan = 4 \times Vs \times \frac{Vs}{10000}$	
	Vd	cm/s	Refer to the speed measurement M	
	Pressure (Vd)	mmHg	Formula: $Tekanan = 4 \times Vd \times \frac{Vd}{10000}$	
	Vmean	cm/s	Refer to the speed measurement M	
	Pressure (VMean)	mmHg	Formula: $Tekanan = 4 \times VMean \times \frac{VMean}{10000}$	
	TVI	cm		
	SD		Formula: $SD = \frac{Vs}{Vd}$	
	RI		Formula: $RI = \frac{(Vs - Vd)}{Vs}$	
	PI		Formula: $PI = \frac{(Vs - Vd)}{Vmean}$	
	HR (single wave)	bpm		

**6.30 PW Urology Measurement**

Refer to the general measurement of PW

**6.31 PW Small parts Measurement**

Refer to the general measurement of PW

**6.32 PW Pediatric Measurement**

Refer to the general measurement of PW

## CHAPTER 7 PRESET

This chapter describes the operations for system settings via a preset menu that has been set previously (presets). The preset function is used to set the working environment and status, parameters of each exam mode. The settings will be stored in the system memory and are not lost even after the system shuts down. When the system is activated, it will work automatically with the status required by the operator.

In the preset interface, all operations depend on moving the trackball to the button position of the required function. Press [ENTER] to start the operation.

### 7.1 General Settings



General Settings Interface

Press [SETUP] to enter the system setup interface. Users can make user-based settings. Press [X] on the title bar or exit button to exit the general settings interface.

Function Name	Setting Method	Function Description
Hospital, department	Free input	Sets the hospital name displayed at the top left of the "General Settings" dialog box, a maximum of 20 characters can be entered.
Date and time	Free input	Set date (calendar format), select current date directly. The date format can be changed by setting the format.
Date format	Free to set	Set the date format: Year/Month/Date, Month/Date/Year, Date/Month/Year.
time zone	Free to set	Setting the clock on the system
Screen controller	Select function and set start time	Activate the screensaver, the user can customize the screensaver image, the image named "screensaver", JPG, PNG, BMP format, the size does not exceed 512*384 pixels
Language	Select a language	Select the language for the operating interface (Mandarin, English and so on)
Screen Shot Type	Choose the type you need	Set the content on the screen image: only images, image fields and patient information, full screen.
Selection of Number of Frames	Free to set	Sets the default frame when saving movies.

Options for drawing area	Click the button to open the settings box	Set the STC curve, including always show, always hide and hide from 1 to 8 seconds.
Options for sent images	Click the button to open the settings box	Adjust parameters from the sent image: brightness, contrast and gamma
Option to print images via PC	Click the required mode and open the setting box to select different parameters	Includes print area and setting conditions on the drawing interface.
Default	Press the button	Restore all presets to factory settings

## 7.2 Measurement

Measurement includes general measurement settings and measurement formula settings.

### 7.2.1 General Measurement Setting

General settings can only change the appearance of the unit of measurement.

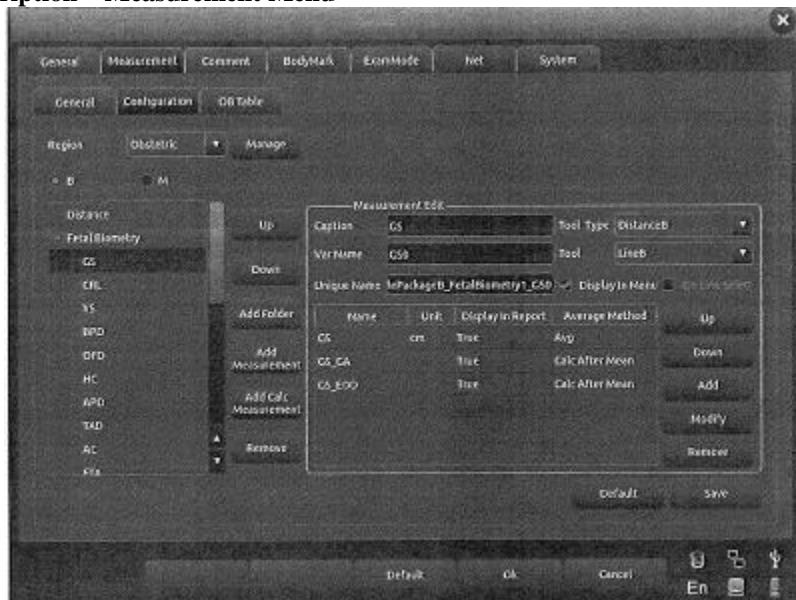


General settings interface

- Distance: cm, mm
- Area: cm<sup>2</sup>, mm<sup>2</sup>
- Volume: ml, l
- Time: s, m
- Speed: cm/s, mm/s
- Acceleration: cm/s<sup>2</sup>, mm/s<sup>2</sup>
- Angle: deg, rad
- Weight: g, kg
- Measurement options: clean result from unfreeze, and auto freeze image
- Measurement results: the color of the result writing size is alternative, including yellow/white/orange/green
- Follicle: way to measure follicles, you can choose two spacing and three spacing

## 7.2.2 Measurement Formula Setting

### 7.2.2.1 Interface Description – Measurement Menu

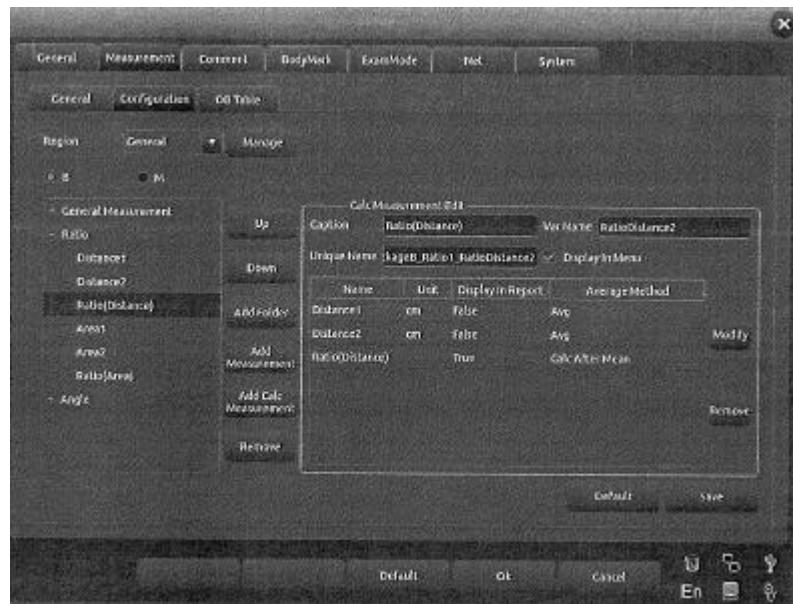


Interface for editing measurement formulas

- Area: pull down and select the required measurement menu
- Settings: bring up the measurement software edition interface, add, modify, delete, replace, sort order in the measurement menu
- B,M,D: display measurements for each exam mode
- Up: press the button to move the measurement term down
- Down: press the button to move the measurement term up
- Add Folder: add measurement items in the left column when the term is not visible, there is a “+” or “-” sign
- Add Measurement: add measurement items in the right column, there is a choice of item and detail parameters.
- Add Measurement Calculation: add a calculation item for the measurement term.
- Delete: delete the selected measurement term
- Save: save user modified measurement items
- Click: displays the required item on the measurement menu, otherwise it is not displayed.

Caption	Displays the names of all items displayed on the measurement menu
Variable Name	Name of the selected built-in measurement menu, users do not need to modify because the display order by name
Unique Name	Built-in code, users do not need to modify
Measurement Rules	None: disables the rule, Repeat: repeats items, Sequential: measures in order
Default Items	After selecting Repeat and Sequential, select a measurement or calculation to activate the measurement rule

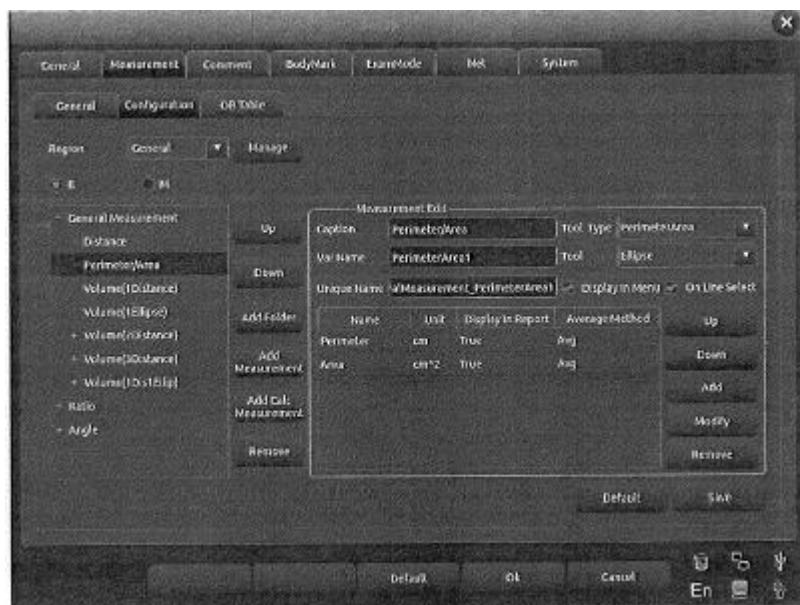
### 7.2.2.2 Interface Description – Measurement Manipulation



Interface for editing measurement formulas

Caption	Displays the names of all items displayed on the measurement menu
Variable Name	Name of the selected built-in measurement menu, users do not need to modify because the display order by name
Unique Name	Built-in code, users do not need to modify
Display on Menu	Check the required items and will be displayed on the measurement menu. Items without a tick will not be displayed on the measurement menu
Choose Measurement Method	Check the method in the measurement menu, press [Update] to switch the method, otherwise the measurement is not available
Display on Report	Check and display the item in the measurement menu, otherwise the item is not displayed
Name	Measurement operation of the specified measurement display on the results
Unit	Unit data resulting from measurement operations.
Display on Report	Is it shown in the report or not
Average method	Average of data rules
Modification	Press this button to bring up the interface for modifying the measurement operation
delete	Press this button to clear the selected measurement operation

### 7.2.2.3 Interface Description – Measurement Calculation



Interface for editing measurement format

Caption	Displays the names of all items displayed on the measurement menu
Variable Name	Name of the selected built-in measurement menu, users do not need to modify because the display order by name
Unique Name	Built-in code, users do not need to modify
Type of tool/tool	Select the types of measurement tools available: Distance B (line B), area/ circumference (ellipse, trace), distance M (vertical line M), time (horizontal line M), slope M (sloping M)
Name	Measurement operation of the specified measurement display on the results
Unit	Unit data resulting from measurement operations.
Up	Press this button to move the measurement operation up
Down	Press this button to move the measurement operation down
Average method	Average of data rules
Plus	Press this button to bring up the interface for adding measurement operations
Modification	Press this button to bring up the interface for modifying the measurement operation
delete	Press this button to clear the selected measurement operation

#### 7.2.2.4 Create Measurement Operations

Press [Add] on the measurement operation interface, a dialog box will appear as follows

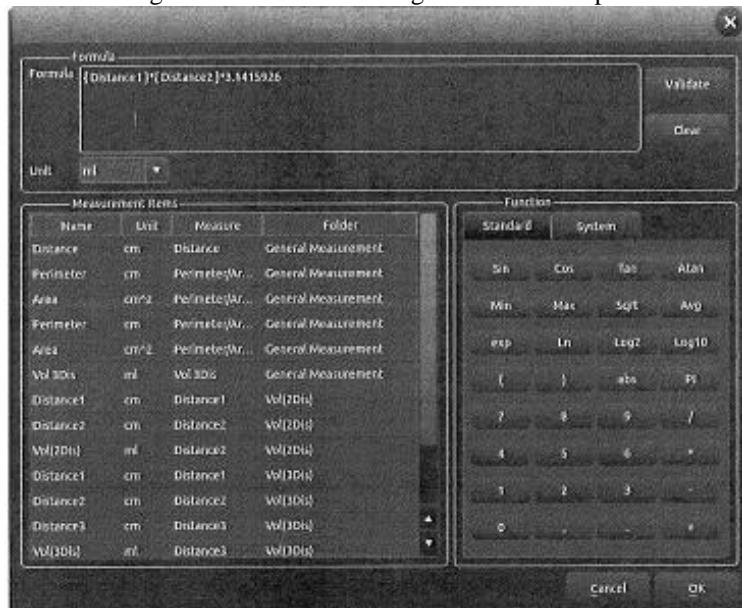


Interface for editing measurement formulas

Caption	Displays the names of all items displayed on the measurement menu
Variable Name	Name of the selected built-in measurement menu, users do not need to modify because the display order by name
Unique Name	Built-in code, users do not need to modify
Rule result	Setting operations required for certain measurements and calculations
Edit	Measurement operation of the specified measurement display on the results
Maximum	Maximum value displayed in result zone and report
Minimum	Minimum values displayed in result zones and reports
Unit	Unit data resulting from measurement operations.
Display on Report	Is it shown in the report or not
Average method	Average of data rules

### 7.2.2.5 Formula Edit – Normal

It is necessary to enter into the following interfaces when making measurement operations except OB.



Interface for editing measurement formulas

- Formulas: edit formulas in input boxes via keyboard and built-in formulas.
- Validation: press this button to check whether the formula is correct or not after editing the formula.
- Delete: delete the content in the input box.
- Unit: selects the unit from the calculation.
- Measurement Items: displays all available measurement operations in the measurement menu.
- Functions: built-in formula, number of inputs, and some necessary parameters such as BSA, SPSA etc
- Cancel: cancels the edited formula and closes the interface.
- OK: save the edited operation and close the interface.

### 7.2.2.6 Formula Edit– OB

It is necessary to call the built-in OB formula sheet when creating OB measurement operations. The following function operation interface is required.

**⚠ WARNING:** GA and EDD results do not require units, units of this class are built-in.



Measurement Items: displays the current created measurement term

OB table: Built-in OB formula table

List OB



- Measure Item: OB pengukuran measurement item
- GA table: gestational list for current measurement project
- Growth Table: growth table for current measurement
- Fetal Weight: formula for calculating fetal weight
- EFW equation: fetal weight calculation for current measurement.
- EFW growth: fetal weight growth curve for current measurement
- Information: displays gestational age and fetal weight for current measurement
- Cancel: cancel the operation of the formula selection
- Save: save formula selection by user

### 7.3 Annotations



Annotation Settings Interface

#### 7.3.1 Annotation Library

The annotation database of the system is classified as: Abdomen, OB, GYN, heart, small organs, and pathological changes. Annotations can be created by entering characters from the keyboard or calling up terms stored in the annotation database.

Press the [Comment Lib] drop-down button, the annotation name appears in the system, via the trackball and [ENTER] to display the required annotation status.

#### Editing Annotation Library

Operation:

1. In the annotation status, move the cursor to the [Edit Comment Type] button then press [ENTER]; annotations will be updated, and can be edited.
2. Enter a name in the new annotation status box, move the cursor to [Create] then press [ENTER], then create a new annotation status and appear in the list of selected annotation statuses in the list.
3. Move the cursor to the [Delete] key, press [ENTER], then delete the current annotation state in the selected annotation list.
4. Change the name of the current annotation state on the list in the [Current Type Name] input box, press [ENTER] on [Rename], then change the name of the selected annotation state

**⚠ NOTES:** Factory setting comments cannot be deleted or renamed.

#### 7.3.2 Edit Annotations

The operator only uses the current annotation rather than all the content of the annotation state that provides the general annotation. If needed, users can import annotations or self-created annotations into general annotations.

##### 7.3.2.1 Adding annotations from the annotation library

Operation:

1. Select the required annotation source status via Trackball and [ENTER].
2. Select the required annotation in the [Comment Lib] column then press [ENTER] to activate the annotation.
3. Press [ENTER] on the [>] key to import the selected annotation to the user-selected annotation state; press [ENTER] on [>>] to move the annotation selected in [Comment Selected] to the annotation source.
4. Press [ENTER] on [>>] to import all annotations in the source to the user-selected annotation state; press [ENTER] on [>>>] to move all annotations in the [Comment Selected] column to the annotation source.

### 7.3.2.2 Adding annotations manually

Operation:

1. Activate the [Edit Comment] input box via the trackball and [ENTER], then enter the required abbreviation and the full name of the annotation.
2. Press [ENTER] on the [Add] button, meanwhile this handout will be added to the user-selected source and status explanation.

### 7.3.2.3 Changing annotations

Operation:

1. Change the status of the user-selected annotation, the abbreviation and full name of the annotation will be displayed in the [Edit Comment] box.
2. Activate required abbreviations and full names via [ENTER] and change them via keyboard.
3. Press [ENTER] on the [Modify] key, modifying the annotations in both the source and the user-selected state.

### 7.3.2.4 Delete annotation libraries

Operation:

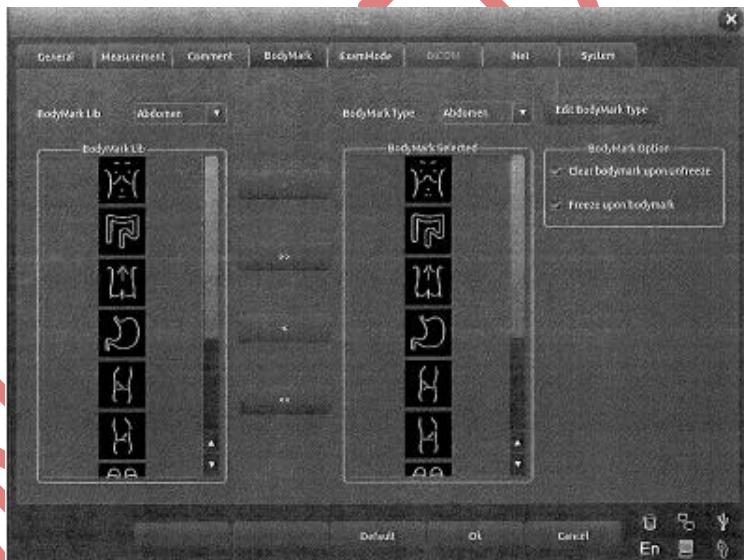
Select the required annotation in source state, press [ENTER] on [Delete from Lib] then the annotation is deleted.

### 7.3.3 Comment and Arrow Options

Optional: do clear comments and arrows on unfreeze.

Optional: whether to freeze over comments and arrows.

## 7.4 Bodymark



Bodymark Settings Interface

### 7.4.1 Bodymark Library

Built-in bodymarks: abdomen, OB, GYN, heart, small organs, urology, vessels.

Press the drop down button [BodyMark Lib], the name of the built-in bodymark appears, display the required bodymark via the trackball and [ENTER].

#### 7.4.1.1 Edit Bodymark Library

Operation:

1. Press [ENTER] on [Edit BodyMark Type], an edit box appears.
2. Enter a name into the created bodymark box, move the cursor to the [Create] key then press [ENTER], then a new bodymark will be created and appear in the list of selected bodymarks.
3. Move the cursor to the [Delete] key then press [ENTER], and then delete the bodymark in the currently selected list.
4. Change the annotation name in the current status list in the [Current Type Name] input box, press [ENTER] in

[Rename], then rename the selected bodymark.

#### 7.4.1.2 Edit Bodymark

Operation:

1. Select the required bodymark source via the trackball and [ENTER].
2. Select the required bodymark in the [BodyMarkLib] column then press [ENTER] to activate it.
3. Press [ENTER] on [>] to import the selected bodymark to the user-selected state; Press [ENTER] on [>] to move the selected bodymark in the [BodyMarkSelected] column into the bodymark source.
4. Press [ENTER] on [>>] to import all user-selected status dark bodymark sources; Press [ENTER] on [>>] to move all bodymarks in the [BodyMarkSelected] column to the source.
5. Press [ENTER] on [Move Up] to move the selected bodymark up; Press [ENTER] on [Move Down] to move the selected bodymark down.

#### 7.4.3 Bodymark Options

Optional: do clear bodymark and arrow on unfreeze.

Optional: whether to freeze over the bodymark.

### 7.5 Exam Mode

#### 7.5.1 Exam Mode Edit

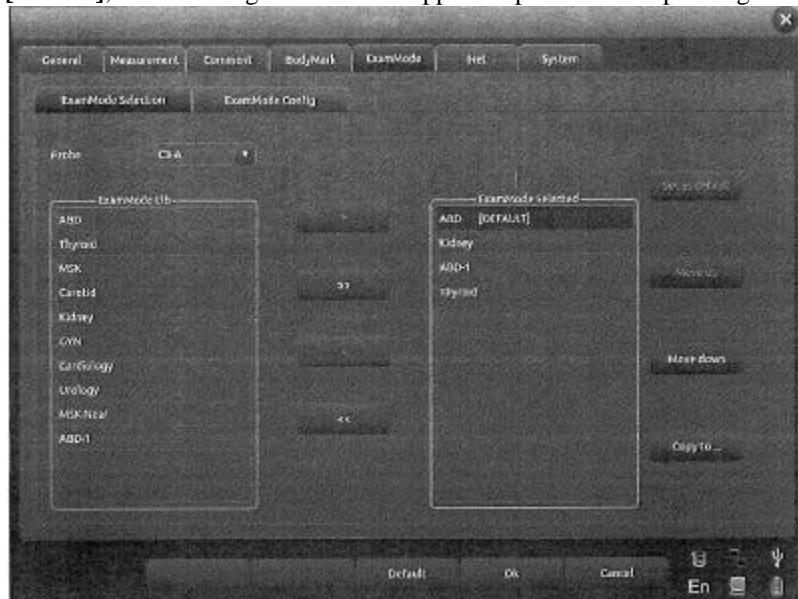
Press Utility in the submenu of [MENU], the parameter setting area is displayed as follows. Press the appropriate parameter button to turn the function off or on.



- Presets: Displays the current preset
- Rename: Rename the current preset
- Load Preset: Load the displayed preset
- Save: Saves the current preset
- Save As: Saves the current preset as another.

### 7.5.2 Exam Mode Selection

Select utility and press [MENU], the following interface will appear. Open the corresponding function in the settings area.



Interface for Check Mode Setting

- Probe: select the required probe and suitable probe mode accordingly.
- ExamMode Lib: displays all examination modes.
- ExamMode Selected: displays the examination mode in the probe column.
- >: import the selected examination mode from the ExamModeLib column to ExamMode Selected.
- >>: import all examination modes from ExamModeLib column into ExamMode Selected column.
- <: removes the examination mode in the ExamMode Selected column.
- <<: clears all examination modes in the ExamMode Selected column.
- Set as default: the selected examination mode setting in the ExamMode column as default.
- Move up: moves the examination mode selected in ExamMode Selected up.
- Move down: moves the examination mode selected in ExamMode Selected up.
- Copy to: copies the selected examination mode in ExamMode to a specific preset.

### 7.5.3 Exam Mode Selection

Operator can create required exam mode in detail including annotation, bodymark, measurement menu import, export, etc.

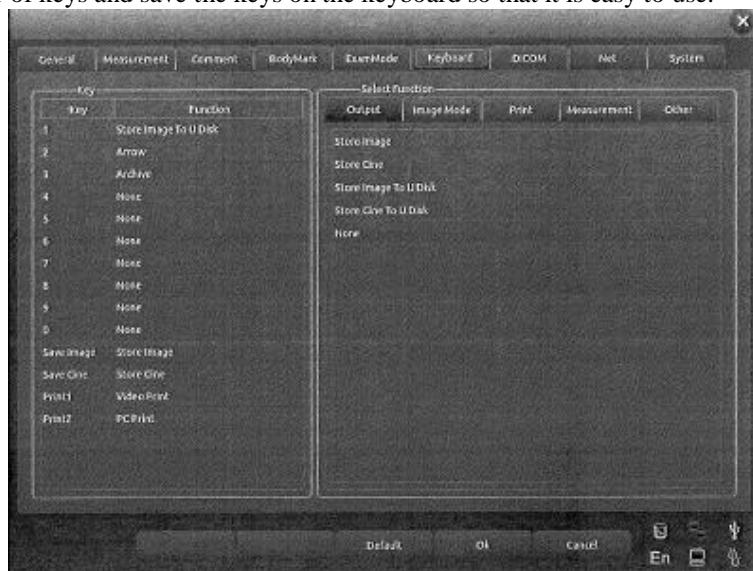


Check Mode Setting Interface

- ExamMode: displays all examination modes present in the system.
- Comment: press [ENTER] twice to activate the widget box, can select the annotation name status. After setting, the default of the exam mode is selected by the user.
- BodyMark: same as comments, select the default bodymark the user needs.
- Measurement: same as comments, select the default measurement menu that the user needs.
- Rename: renames the selected examination mode.
- Delete: deletes the selected exam mode.
- Export: export all built-in exam modes to a USB flash disk.
- Import: import all built-in exam modes into a USB flash disk.
- Restore: restore all check mode to factory settings.

## 7.6 Keyboard

Users can set the number of keys and save the keys on the keyboard so that it is easy to use.



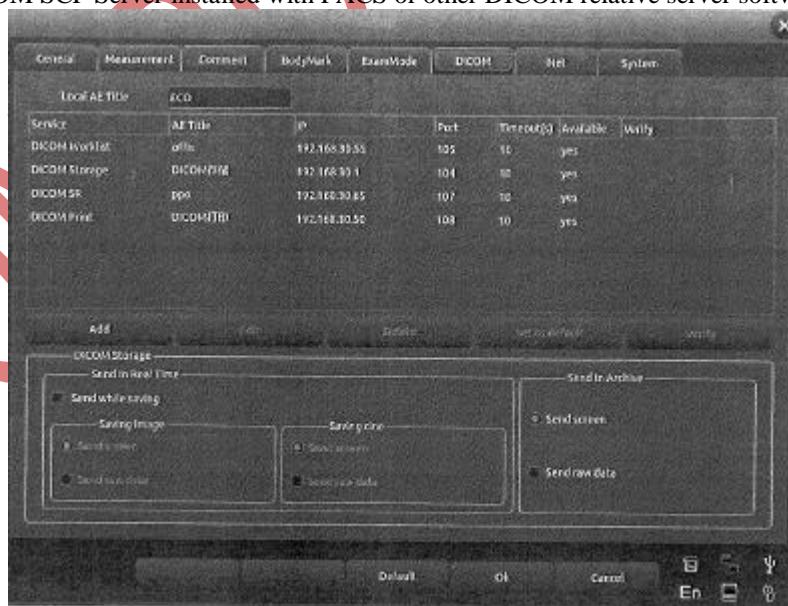
Keyboard Settings Interface

- Output: includes saving images, saving movies, saving images to U disk, and other functions.
- Image mode: includes full screen image, biopsy, chroma, etc
- Print: including video print, PC print, etc
- Measure: including GS, CR, BPD, HC, AC, etc
- Others: including arrows, archive

## 7.7 DICOM

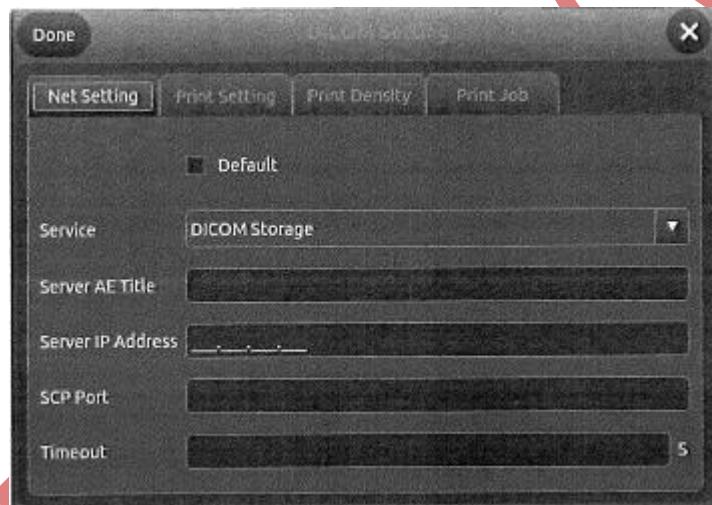
DICOM includes DICOM storage, DICOM worklist, DICOM print, and DICOM SR. If DICOM is implemented, make sure DICOM is enabled. In the system settings interface page, you can check whether DICOM is open or not. If you want to activate DICOM, please contact PT. Sinko Prima Alloy.

Required to have DICOM SCP Server installed with PACS or other DICOM relative server software.



- Local AE title: enter a local DICOM title to separate the DICOM equipment on the local network.
- Service: displays local DICOM worklist functions.
- AE title: displays the local AE DICOM title name.
- IP: displays the IP of the DICOM server.
- Port: displays the DICOM server port.
- Timeout(s): displays the delay time.
- Available: displays whether DICOM is the default or not.
- Verify: Press the verify button and display whether the DICOM settings are correct or not.
- Add: adds DICOM functionality and brings up the settings dialog.
- Delete: deletes an existing DICOM function.
- Set as default: sets one DICOM service as default.
- Send while saving: check this item and open DICOM storage while saving image or cine, send clip or image according to enabled function.
- Send in archive: send DICOM storage in archive or review; send clips or pictures according to the activated function.

#### Add/Edit DICOM Functions



- Default: check this option, set DICOM function as default.
- Service: selects DICOM storage, DICOM worklist, DICOM print, or DICOM SR.
- Server AE Title: enter DICOM Server AE name.
- Server IP Address: enter the DICOM IP address.
- SCP Port: Enter the DICOM SCP server port.
- Timeout: set the delay time from DICOM.

**TIPS:** selecting the DICOM print type must be before the relative print settings.

#### 7.8 NET Network

Set the unit and target IP then test connection and network storage settings, for more details see attachment: Procedure for setting up network share in PRA-ONE

#### 7.9 System

##### 7.9.1 System Information

Displays software version, system version, etc

### 7.9.2 Upgrade

Software and Hardware can be updated with a USB flash drive.  
Software Upgrade File Path: X:\update\XXX or X:\update\_SN\XXX.  
Hardware Upgrade File Path: X:\fpga\_update\XXX  
Keyboard Upgrade File Path: X:\keyboard\_update\XXX  
X stands for USB flash drives, XXX stands for update content. It is required to restart the hardware update manually, and after the software update, the machine can be restarted automatically.

### 7.9.3 Function Setting

DICOM: Click the [Open] button, the DICOM input dialog box button will appear. Input DICOM SN, and click [OK] to save and exit.  
Full Screen Show: refers to DICOM.

### 7.9.4 Installation Settings

Enter the relevant button to open the trial function and details please contact PT. Sinko Prima Alloy.

### 7.9.5 Video VGA

Choose video data: NTSC, PAL-M, and PAL-D.  
Video opened: Select the item to open this function.  
VGA opened: Select the item to open this function.

### 7.9.6 Image Function

Export SN hardware and import hardware keys, only for technicians to do.

### 7.9.7 System Maintenance

Only an authorized technician is allowed to perform maintenance.

### 7.9.8 USB Video Printer Options

Adjust the parameters of Video Printer Option: Dark, Light, Sharpness, and Gamma.  
Select the required parameters to adjust, press [Confirm] on the parameter slider, and move the trackball to change the parameters.

## CHAPTER 8 SYSTEM MAINTENANCE

### 8.1 Machine Cleaning

**⚠️ WARNING:** turn off the power before cleaning and unplug the cable from the socket. There is a possibility of electric shock if the device is turned on

#### Cleaning method:

Use a soft dry cloth to wrap the machine. If the device is quite dirty, use a damp soft cloth. After wiping the stain, use a soft dry cloth to wipe dry

**⚠️ WARNING:**

1. Do not use organic solvents such as alcohol, otherwise the surface of the device may be damaged.
2. When cleaning the machine, do not allow liquid to enter, otherwise it may cause malfunction and there is a danger of electric shock.
3. If it is necessary to clean the probe connectors and additional instruments, please contact customer service or an agent of PT. Sinko Prima Alloy. Any self-cleaning may result in malfunction or deterioration of the device

### 8.2 Probe Maintenance

The probes used by this machine can be divided into two series: body surface and intracavitory. During an ultrasound scan, the ultrasonic radiation on the human body should be kept to a minimum.

**⚠️ CAUTION:**

1. Only people who have received professional training can use the probe.
2. The probe cannot accept pressure sterilization, when operating in a sterile area, a disposable probe sterile cap should be used.
3. Be sure not to drop the transducer on a hard surface. This can damage the transducer elements and reduce the electrical safety of the transducer.
4. Be careful when operating, making sure not to scratch the surface of the probe.
5. Avoid twisting or pinching the transducer cable.
6. Be sure not to plug the probe into the socket or place the cable near any liquid
7. Keep the probe clean and dry. Turn off or freeze the probe when repairing or removing the probe.
8. Be sure not to use or store the probe in an environment above 50 degrees.
9. If abnormal probe abnormal phenomenon is found, stop operation immediately and contact the sales staff, customer service, or agent of the manufacturer.

#### Cleaning

The cleaning procedure is appropriate for all probes. After operation, each probe must be cleaned according to the procedure stated in this section. Examination should be performed for the intracavitory probe depending on the conditions of use.

#### Cleaning Procedure:

1. Wipe off any remaining gel and stains with clear running water. Avoid the connection between the cable and the probe touching water or other things.
2. Use a damp gauze or other soft cloth with a small amount of liquid soap to clean the probe. Do not use abrasive cleaning agents.
3. Use running water to rinse. Use a soft cloth that has been soaked in 70% isopropyl alcohol for scrubbing. Then check the probe to make sure there are no smudges.
4. Use a clean cloth to dry the probe.

**⚠️ WARNING:** Do not place the probe surface in liquid under the acoustic lens. The intracavity probe cannot exceed the insertion region. Do not place the probe connector into any liquid.

#### Infection

Appropriate infection procedures are used for intracavitory probes.

If it is necessary to use in surgery, please comply with the instructions of the infection professional.

**Infection Procedure:**

1. Follow the cleaning procedure to thoroughly clean the probe.
2. Prepare a 2% glutaraldehyde solution as an infection solution according to the manufacturer's instructions.
3. Insert the insertion region of the probe into the infection solution, the insertion depth cannot exceed the insertion region. Do not allow the probe connector to touch any liquid.
4. Soak the probe for 3 hours.
5. Pull out the probe, rinse immediately with sterile water and saline to ensure no solution remains. Please adhere to the rules for performing proper rinsing procedures including sufficient rinsing water and cleaning time.
6. When the probe is used in a sterile area, be sure to use a disposable sterile probe cap.

**CAUTION:**

1. Do not immerse the probe connector in any liquid.
2. Do not allow the immersion depth of the intracavitory probe to exceed the insertion region.
3. Do not immerse the probe in liquid for more than 12 hours.
4. Use only quality examination resolutions.

**Storage:**

Place the probe in a clean and dry environment, avoid direct sunlight.

Keep the environment for placing the probe between -10 – 50OC, do not expose the probe to high pressure and vacuum environment.

Be careful when using the probe and avoid damaging it.

During transportation, the probe should be stored in the probe box.

**8.3 Safety Check**

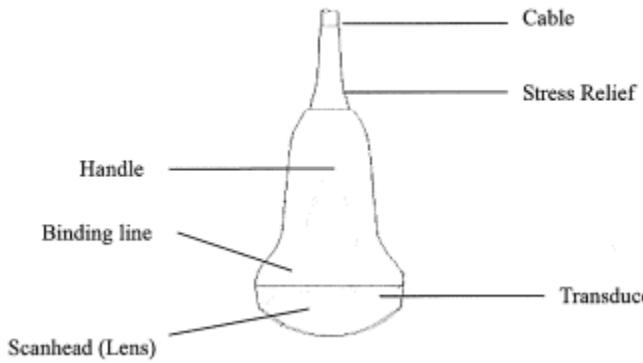
To ensure this device is working normally, it is recommended that a maintenance plan be made to check the device regularly. If there is an abnormal phenomenon, stop operation immediately and contact the sales staff, customer service, or agent of the manufacturer. If there is no picture or there is a picture but no menu, check the malfunction table as follows. If the malfunction cannot be resolved, please contact the sales staff, customer service or an agent of the manufacturer.

**8.4 Malfunction Check**

Serial Number	Malfunction	Reason	Measurement
1	The switch button is on but the power button is not	Battery loses effectiveness, adapter doesn't work well	Check the connection between the cable and the power source
2	The power button is on but there is no LED image	The interval time is too short to restart	Restart after 1 minute
3	LED displays menu characters but no scan image	STC power, gain or control error. Not connected with probe or probe connection is not correct. The device is in a frozen state.	Set the ignition power, gain, or STC control. Ensure proper connection. Get out of the frozen state
4	Abnormal picture	Error checking mode. Error image processing settings.	It is possible due to improper exam mode or not adjusting image processing settings or setting as default
5	Probes are not working properly	1. Loose socket 2. Internal circuit security	1. Remove the probe and reinser it 2. Restart
6	No OB calculation package	Don't select OB app before scanning	Select OB app
7	PRINT button not working	1. The connected printer is not approved 2. The power source doesn't work 3. Printer is not connected properly	1. Change approved printer 2. Turn on the printer 3. Reconnect the printer

## CHAPTER 9 PROBE

### 9.1 General Description



Convex Probe Overview

The probe provides spatial processing and high contrast ultrasound with frequencies from 2.0MHz to 11.0MHz. This probe operates by emitting sound waves into the body and receiving echoes back to produce a high-resolution brightness mode, and real time display.

### 9.2 Care and Maintenance

The probes in the system are designed to be durable and reliable. These precision instruments must be inspected daily and handled with care. Please take the following precautions:

1. Do not drop the transducer on a hard surface. This can damage the transducer elements and reduce the electrical safety of the transducer.
2. Avoid folding or pinching the transducer cable.
3. Use only approved ultrasonic gels.
4. Follow the instructions for cleaning and disinfection that comes with each probe.

#### 9.2.1 Probe Inspection

*Before and after use, carefully inspect the probe lens, cable, case, and connector: Look for any damage that might allow liquid to enter the probe. If damage is found, do not use the probe until the probe has been inspected and repaired/replaced by an authorized technician.*

##### NOTES:

*Keeps a log of all probe maintenance, along with pictures of any probe malfunctions.*

##### WARNING:

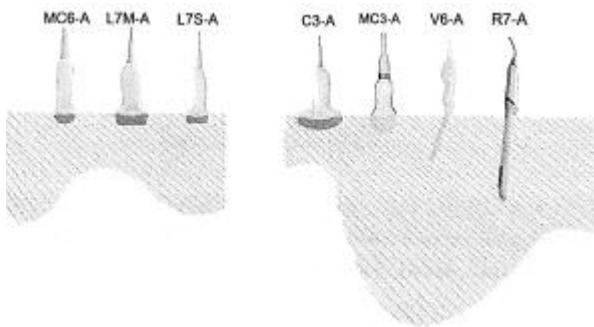
*The probe is designed for use only with this ultrasound system. Using this probe on other systems or an unqualified probe may result in electric shock or damage to the system/transducer.*

#### 9.2.2 Cleaning and Disinfecting

- Place the probe into the cleaning-disinfectant solution. Be sure not to immerse the probe in liquid beyond the level of immersion given in the figure below. Ensure that the probe is immersed with the cleaner-disinfectant to the level of immersion during the entire disinfection time.
- For recommended cleaning and disinfection times, please refer to your operating instructions.
- Rinse the probe with sufficient clean drinking water, to remove all disinfectant residue.

- Use a soft cloth to clean cables and probe parts used with a disinfectant-cleaning solution. Make sure that the surface of the probe and cable is thoroughly moistened with a disinfectant-cleaner.
- Allow the probe to air dry completely.
- Reconnect the probe to the ultrasound console and place the probe in the holder.

### Probe Immersion Level



#### **⚠️ WARNING:**

This transducer is not designed to withstand heat sterilization methods. Exposure to temperatures over 60°C will cause permanent damage. Transducers are not designed to be completely immersed in a liquid, permanent damage will occur if the entire transducer is submerged.

### Probe Safety

#### **Handling precaution**

Ultrasound probes are very sensitive medical instruments that are easily damaged by improper handling. Be careful when using and protect against damage when not in use. DO NOT use a damaged or defective probe. Failure to follow these precautions could result in injury and serious equipment damage.

#### **Electrical Shock Hazard**

The probe is driven by electrical energy which can injure the patient or user if live internal parts are connected by a conductive fluid:

- DO NOT immerse the probe in a liquid beyond the level indicated by the level of immersion of the probe. Do not immerse the probe connector in any liquid.
- Before use, check the probe lens and areas for cracks, cuts, tears, and other signs of physical damage. DO NOT use a probe that appears damaged until you have verified its functional and safe performance. You will need to do a more thorough check, including cables, and connectors, each time you clean the probe.
- Before inserting the connector into the probe port, check the probe connector pins. If the pin is bent, DO NOT use the probe until the probe has been inspected and repaired/replaced by an authorized PT. Sinko Prima Alloy.
- Electrical leakage checks must be carried out regularly by authorized technicians of PT. Sinko Prima Alloy or qualified hospital staff.

#### **Mechanical Hazard:**

A faulty or overloaded probe can cause patient injury or probe damage:

- Observe depth markings and do not apply excessive force when inserting or manipulating the endocavitory probe.
- Check for sharp edges or rough surfaces on the probe that could injure sensitive tissue.
- DO NOT apply excessive force to the probe connector when inserting it into the probe port. The probe connector pins can be bent.

#### **Special handling instructions**

##### **Using protective sheaths**

The use of clear protective sheaths on the market is recommended for clinical applications. FDA reference March 29, 1991 "Medical Alert on Latex Products".

Protective gloves may be required to minimize disease transmission. The probe protective sheath is available for use with all clinical situations where infection is feared. It is strongly recommended to use a sterile probe protective sheath which is marketed legally for endocavitory procedures.

DO NOT use a lubricated condom as a sheath. In some cases, this can damage the probe. The lubricant in this condom may not be compatible with the probe construction.

Devices containing latex can cause severe allergic reactions in latex sensitive individuals. Referring to the FDA March 29, 1991 "Medical Alert on Latex Products".

DO NOT use expired probe safety sheaths. Before using a safety glove, verify if it has expired.

### **Endocavitory Probe Handling Precaution**

If sterilizing fluid leaks from the endocavitory probe, follow the precautions below:

**Exposure to sterilization for the Patient (eg, Cidex):** Contact with sterilization of the patient's skin on the mucous membranes can cause inflammation. If this occurs, refer to the instruction manual of the sterilizer.

**Exposure Sterilization from Probe to Patient (eg Cidex):** DO NOT allow the sterilizer to come into contact with the patient. Only immerse the probe to the specified level. Ensure that no liquid enters the probe handle before scanning the patient. If the sterilizer comes in contact with the patient, refer to the sterilization instructions.

**Exposure Sterilization from Probe Connector to Patient (E.g. Cidex):** DO NOT allow the sterilizer to come into contact with the patient. Only immerse the probe to a predetermined level. Ensure that no liquid enters the probe connector before scanning the patient. If the sterilizer is in contact with the patient, refer to the sterilization manual.

**Endocavitory Probe Point of Contact:** Refer to the sterilization manual.

### **Probe Handling and Infection Control**

This information is intended to increase user awareness of the risk of disease transmission associated with the use of this equipment and to provide guidance in making decisions that directly affect the safety of patients and users of the equipment.

Diagnostic ultrasound systems utilize ultrasound energy which must be coupled to the patient through direct physical contact. Depending on the type of examination, this contact occurs with various tissues ranging from the skin in routine examinations to blood circulation in surgical procedures. The level of risk of infection varies greatly depending on the type of contact.

One of the most effective ways to prevent transmission between patients is to use a single-use device or device. However, ultrasound transducers are complex and expensive devices that must be reused between patients. It is very important, therefore, to minimize the risk of disease transmission by using barriers and through proper processing between patients.

### **Risk of Infection**

ALWAYS clean and sterilize the probe between patients to a level appropriate for the type of examination and use the appropriate FDA probe holster.

Adequate cleaning and disinfection is necessary to prevent disease transmission. It is the responsibility of the equipment user to verify and maintain the effectiveness of the infection control procedures used. Always use sterile, legally marketed probe sheaths for intra-cavitory procedures.

### **Probe Cleaning Process:**

DISCONNECT the probe from the system before cleaning/disinfecting the probe. Failure to do so may damage the system

### **Probe Cleaning after Each Use**

- Remove the probe from the ultrasound console and remove all gel from the probe by wiping with a soft cloth and rinsing under running water.
- Wash the probe with mild soap in lukewarm water. Rub the probe as needed using a soft sponge, gauze, or cloth to

remove any visible residue from the surface of the probe. Prolonged soaking or scrubbing with a soft bristle brush (such as a toothbrush) may be necessary if the material has dried onto the probe surface.

**⚠️WARNING:**

*To avoid electric shock, always turn off the system and remove the probe before cleaning the probe.*

**⚠️CAUTION:**

*Be careful when handling the lens surface of the ultrasound transducer: the lens surface is very sensitive and can be easily damaged by rough handling. DO NOT use excessive force when cleaning the lens surface.*

*Rinse the probe with enough clean drinking water to remove any visible soap residue. Air dry or a soft cloth.*

**⚠️CAUTION:**

*To minimize the risk of infection from blood-borne pathogens, you should handle the probe and all materials that have been in contact with blood, other potentially infectious materials, mucous membranes, and skin in accordance with infection control procedures. You should wear protective gloves when handling infectious materials. Use a face shield and medical gown if there is a risk of splashing.*

## **Probe Disinfection**

After each use, please sterilize the probe. Ultrasound probes can be disinfected using a chemical disinfectant. The degree of disinfection is directly related to the duration of contact with the disinfectant. Increased contact time results in higher rates of disinfection.

For the disinfectant to be effective, all visible residue must be removed during the cleaning process. Clean the probe well, as described before attempting disinfection.

You must remove the probe from the system before cleaning/disinfecting the probe. Failure to do so may damage the system.

DO NOT immerse the probe in the disinfectant for longer than the instructions for the disinfectant used. Prolonged immersion may result in probe damage resulting in a possible electric shock hazard.

- Prepare the disinfectant according to the manufacturer's instructions. Be sure to follow all precautions for storage, use and disposal. Transducers are not designed to be completely immersed in a liquid. Permanent damage will occur if the entire transducer is submerged. The submerged portion must not extend beyond the transducer edge.
- Place the probe clean and dry in contact with the disinfectant for the time specified by the disinfectant manufacturer. High-level disinfection is recommended for probe surfaces and is required for endocavitory probes (follow the germicidal manufacturer's recommended time).
- Once removed from the disinfectant, rinse the probe following the rinse instructions from the manufacturer of this disinfectant. Flush all visible residue from the probe and allow to air dry.

Ultrasound transducers can be easily damaged by improper handling and contact with certain chemicals. Failure to follow these precautions could result in serious injury and equipment damage.

- Do not immerse the probe in liquid beyond the level specified for the probe. Never immerse the transducer connector or probe adapter in any liquid
- Avoid mechanical impact on the transducer and do not use excessive force to fold or pull the cable.
- Transducer damage can result from contact with an inappropriate cleaning fluid.
- Do not immerse or immerse the transducer in liquids containing alcohol, bleach, ammonium chloride, or hydrogen peroxide.

- Avoid contact with liquids or gels that contain mineral oil or lanolin.
- Avoid temperatures above 60°C. Under no circumstances can the transducer use the heat sterilization method. Exposure to temperatures above 60°C will cause permanent damage to the transducer.
- Check the probe before use for any damage or degeneration of the housing, lens, seals, etc. Do not use damaged or deformed probes.

## Coupling Gel

DO NOT use a non-recommended gel (lubricant). The gel may damage the probe and void the warranty.

Gel recommendation: Aquasonic Gel by R. P Kincheloe Company (United States).

To ensure optimal transmission of energy between the patient and the probe, the conductive gel must be evenly applied to the patient where the scan is to be performed.

### CAUTION:

*Do not use gels or other materials not provided by PT. Sinko Prima Alloy. Gels, lubricants and other materials can corrode the probe and other parts of the device, such as the keyboard. This can reduce the safety and effectiveness of the system and probe, and can also reduce the life time of the system and probe. Damage caused by reasons as above is not covered by the warranty.*

DO NOT apply the gel to the eyes. If gel comes into contact with eyes, flush eyes with clean water. The coupling gel must not contain any of the following ingredients as these are known to cause probe damage:

- Methanol, ethanol, isopropanol or other alcohol-based products.
- mineral oil
- Iodine
- Lotion
- Lanolin
- aloe vera
- Olive oil
- Methyl or Ethyl Paraben (Parahydrobenzoic Acid)
- Dimethyl Silicone

## Planned Maintenance

The following maintenance plans are recommended for the system and probes to ensure optimal operation and safety.

**Daily:** check the probes.

**After each use:** clean the probe, sterilize the probe.

**Necessary:** inspect the probe, clean the probe, and disinfect the probe.

## Returning/Shipping of Probes and Repair Parts

Our transportation department and policies require that equipment returned for service MUST be clean and free of blood and other infectious substances.

When you return a probe or part for service, you will need to clean and sterilize the probe or part prior to packing and shipping the equipment.

Make sure that you follow the probe cleaning and disinfection instructions given in this manual.

This ensures that employees in the transportation industry as well as people who receive packages are protected from any risk.

## AIUM's Endocavitory Transducer Cleaning Outline

Guidelines for Cleaning and Preparation of Endocavitory Ultrasound Transducers among Patients from AIUM

Approved June 4, 2003

The purpose of this document is to provide guidelines regarding the cleaning and disinfection of transvaginal and transrectal ultrasound probes.

All sterilization/disinfection represented a statistical reduction in the number of microbes on the surface. Careful cleaning of the instrument is an important icon for the initial reduction of the microbial/organic load by at least 99%. This cleaning is followed by a disinfection procedure to ensure a high level of protection from the transmission of infectious diseases, even if disposable barriers cover the instrument during use.

Medical instruments fall into different categories according to their potential for transmission of infection. The most important level of the instrument is that which is meant to penetrate the skin or mucous membranes. This instrument requires sterilization. Less critical instruments (often called "semi-critical" instruments) that only come into contact with mucous membranes such as fiber-optic endoscopes require high-level disinfection rather than sterilization.

Although endocavitory ultrasound probes are considered less critical instruments because they are routinely protected using disposable probe protectors, recent studies suggest a leakage rate of 0.9% - 2% for condoms and 8% - 81% for commercial probe guards. For maximum safety, a high level of disinfection should be carried out on the probe between each use and using a probe cover or condom as an aid in keeping the probe clean.

There are four generally recognized categories for disinfection and sterilization. Sterilization is the complete elimination of all forms of microbial life including spores and viruses. Disinfection is the selective removal of microbial life, divided into three classes:

**High Level Disinfection** - Destruction/removal of all microorganisms except bacterial spores.

**Intermediate Disinfection** - Inactivation of Mycobacterium Tuberculosis, bacteria, most viruses, fungi, and some bacterial spores.

**Low Level Disinfection** - Destruction of most bacteria, some viruses and some fungi. Low-level disinfection will not always inactivate Mycobacterium tuberculosis or bacterial spores.

The following specific recommendations are made for the use of the Endocavitory Ultrasound transducer. Users should also review Central Disease Control and Prevention's documents on sterilization and disinfection of medical devices to ensure that procedures comply with CDC principles for disinfecting patient equipment.

### **1. CLEANING**

After removing the probe cover, use running water to remove any remaining gel or dirt from the probe. Use a soft gauze or other soft cloth and a small amount of mild non-abrasive liquid soap (household dish soap) to thoroughly clean the transducer. Use a small brush especially for crevices and areas of angulation depending on the particular transducer design. Rinse the transducer thoroughly under running water, then dry the transducer with a soft cloth or paper towel.

### **2. DISINFECTION**

Cleaning with a detergent/liquid solution as described above is important as the first step in proper disinfection because chemical disinfectants act more quickly on clean surfaces. However, the additional use of a high-level disinfectant liquid would ensure a further statistical reduction in the microbial load. Because of the potential for disruption of the barrier sheath, additional high-level disinfection with chemicals is required. Examples of such high level disinfectants include but are not limited to:

- 2% glutaraldehyde product (various products available include "Cidex" "Metricide" or "Procide").
- Non-glutaraldehyde agents include Cidex OPA (o-phthalaldehyde), Cidex PA (hydrogen peroxide & peroxyacetic acid).

- 7.5% Hydrogen Peroxide Solution.
- Bleach used in households (5.25% sodium hypochlorite) is diluted to produce 500 parts per million chlorine (10 cc in one liter of tap water). These agents are effective, but are generally not recommended by probe manufacturers because they can damage metals and plastics.

Other agents such as ammonium compounds are not considered high-level disinfectants and should not be used. Isopropanol is not a high-level disinfectant when used as a wipe and probe manufacturers generally do not recommend immersing the probe in liquid.

The FDA has published a list of approved sterilants and high-level disinfectants for use in the processing of reusable medical and dental equipment. This list can be referenced to find agents that may be useful for probe disinfection.

Practitioners should refer to product labels for specific instructions. The practitioner should also consult the device manufacturer regarding the compatibility of the agent with the probe. Many chemical disinfectants are potentially toxic and many require adequate precautions such as proper ventilation, personal protective equipment (gloves, eye/face protection, etc.) and thorough rinsing before the probe is reused.

### **3. PROBE COVERS**

The transducer must be covered with a barrier. If the barrier used is a condom, the condom must be unlubricated and unmedicated. Practitioners should be aware that condoms have been shown to be less susceptible to leakage than commercial probe protectors, and have a sixfold increased AQL (acceptable quality level) when compared to standard examination gloves. It has the same AQL as a surgical glove. Users should be aware of latex-sensitivity issues and provide a non-latex barrier.

### **4. ASEPTIC TECHNIQUE**

For the protection of patients and healthcare workers, all endocavitory examinations should be performed with a gloved operator during the procedure. Gloves should be used to remove condoms or other obstructions from the transducer and wash the transducer as described above. While the barrier/condom is removed, care must be taken not to contaminate the probe with secretions from the patient. At the end of the procedure, hands should be thoroughly washed with soap and water.

 **NOTES:** Obvious impairment in condom integrity does NOT require modification of this protocol. These guidelines take into account the possibility of probe contamination due to interference in the barrier sheath.

Briefly, high-level disinfection of the endocavitory probe between patients, plus the use of a probe cover or condom during the examination is necessary to protect the patient from infection during the endocavitory examination. For all chemical disinfectants, precautions must be taken to protect workers and patients from the toxicity of the disinfectant.

Amis S, Ruddy M, Kibbler CC, Economides DL, MacLean AB. Assessment of condoms as probe covers for transvaginal sonography. *J Clin Ultrasound* 2000; 28:295-8.

Rooks VJ, Yancey MK, Elg SA, Brueske L. Comparison of probe sheaths for endovaginal sonography. *Obstetrics Gynecol* 1996; 87:27-9.

Milki AA, Fisch JD. Vaginal ultrasound probe cover leakage: implications for patient care. *Sterile Fertil* 1998; 69:409-11.

Hignett M, Claman P. High rates of perforation are found in endovaginal ultrasound probe covers before and after oocyte retrieval for in vitro fertilization-embryo transfer. *J Assist Reprod Genet* 1995; 12: 606-9.

Sterilization and Disinfection of Medical Devices: General Principles. Centers for Disease Control, Division of Healthcare

Quality Promotion. <http://www.cdc.gov/ncidod/hip/sterile/sterilgp.htm> (5-2003).

ODE Device Evaluation Information – FDA Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices, March 2003. <http://www.fda.gov/cdrh/ode/germlab.html> (5-2003).

### 9.3 Probe Operating Instructions

For details of connection, activation, deactivation, disconnection, transport and storage of probes.

#### 9.3.1 Scanning Patient

To ensure optimal transmission of energy between the patient and the probe, a conductive gel should be applied evenly to the patient where the scan is to be performed. After the exam is complete, follow the appropriate cleaning and disinfection, or sterilization procedures.

#### 9.3.2 Transvaginal Probe Operation

The transvaginal probe is an endo-cavity probe, for operation safety, please refer to "Care and Maintenance" for cleaning and disinfection.

The temperature at the probe tip is displayed on the screen for monitoring. Temperatures above 43 ° C are not allowed. It also depends on the patient's body temperature. When the probe tip temperature exceeds 43°C, the probe will stop working to protect the patient.

The transvaginal probe should be used with an FDA-approved condom or probe cap. Refer to the following instructions for placing the probe into the condom:

##### CAUTION:

- Some patients may be allergic to natural rubber or medical devices containing rubber. The FDA recommends identifying these patients and preparing to treat allergic reactions immediately prior to the scan.
- Only water-soluble liquids or gels can be used. Petroleum-based or mineral oil-based materials can harm the cover.
- When the transvaginal probe is activated outside the patient's body, the acoustic output level must be reduced to avoid harmful interference to other equipment.

#### Operating Procedure:

- Wear medical sterile gloves
- Take the condom for the package.
- Open the condom.
- Put some ultrasound gel into the condom.
- Take the condom with one hand, and place the probe head against the condom.
- Tighten the condom at the end of the probe grip.
- Confirm the integrity of the condom, and repeat the above steps for the condom if any damage is found.

#### 9.3.3 Cleaning and Disinfecting TV and TR Probes

We strongly recommend wearing gloves when cleaning and disinfecting each endocavitory probe.

- Each time before and after each examination, please clean the probe handle and sterilize the transvaginal and transrectal probes using a chemical disinfectant.
- If the probe is contaminated with body fluids, you must disinfect the probe after cleaning.
- Assume exam waste is potentially infectious and dispose of it in accordance with procedures.

**⚠ CAUTION:**

- Since the probe is not waterproof, you must remove the probe from the system before cleaning or disinfecting it. Before and after each examination, please clean the probe handle and disinfect the transvaginal and transrectal probe using a chemical disinfectant.

**Cleaning**

You can clean the transvaginal and transrectal probes to remove all the gel by wiping with a soft cloth and rinsing under running water. Then wash the probe with mild soap in lukewarm water. Rub the probe as necessary and use a soft cloth to remove any visible residue from the surface of the transvaginal probe. Rinse the probe with sufficient clean drinking water to remove all visible soap residue, and allow the probe to air dry.

**⚠ CAUTION:**

Please remove the cover (if any) before cleaning the probe. (Covers such as condoms can only be used once). When cleaning TV and TR probes, it is important to ensure that all surfaces are cleaned.

**Disinfection**

Glutaraldehyde based liquids have been shown to be very effective for this purpose. Cidex is the only disinfectant that has been evaluated for compatibility with the material used to make the probe.

To maintain the effectiveness of the disinfection solution, a thorough cleaning should be carried out on the probe before disinfecting, making sure that no residue remains on the probe.

**Disinfecting Procedure:**

- Follow all precautions for storage, use and disposal, prepare the disinfectant according to the manufacturer's instructions.
- Place the probe to be cleaned and dried for contact with the disinfectant, being careful not to allow the probe to fall to the bottom of the container which could damage the probe.
- After placing/soaking the probe, rotate and wiggle the probe while it is under the surface of the disinfectant to remove any air pockets. Allow the germicide to remain soaked in the probe. For high-level disinfection, follow the manufacturer's recommended time.
- Follow all precautions for storage, use and disposal, prepare the disinfectant according to the manufacturer's instructions.
- After removing the probe from the disinfectant, rinse the probe according to the rinse instructions provided by the manufacturer.
- Flush any visible residue of the disinfectant from the probe and allow it to air dry.

**9.4 Service Responsibilities**

If the user installs, uses, and maintains the system in full accordance with the installation instructions from PT. Sinko Prima Alloy, operating instructions and service instructions, then the main unit PRA-ONE from PT. Sinko Prima Alloy has a service life of 5 years and probes from PT. Sinko Prima Alloy has a service life of 5 years after being used for exam. The warranty of the system and probe after use for exam as stated in the warranty card.

This system is a proper electronic system. Only authorized technicians of PT. Sinko Prima Alloy which can replace damaged parts. Any assembly, disassembly, handling, repair, or replacement by another person may have a negative impact on the safety and effectiveness of the system and probe, and thereby reduce the life time of the system and probe, and such system and probe will not be covered by PT. Sinko Prima Alloy after improper handling above. Standard maintenance must be carried out by authorized technicians of PT.Sinko Prima Alloy during the product life time.

**CAUTION:**

When life expires, the effectiveness and safety of the system and probe may be severely affected, so it is NOT recommended to continue using the system and probe even if the system and probe appear to be working properly. But if the user still wants to continue using the system and the probe, the user must contact the PT. Sinko Prima Alloy first at the head office of PT. Sinko Prima Alloy to arrange the necessary safety checks and calibrations by authorized technicians of PT. Sinko Prima Alloy. If the service center at the head office of PT. Sinko Prima Alloy provides a calibration certificate for the related system or probe, so users can continue to use the system or probe in accordance with the calibration certificate.

However, if PT. the service center at the Sinko Prima Alloy central office concluded that the system or probe no longer met the safety and effectiveness standards, so the user should immediately stop using the system or probe. Users are expected to understand that the cost of checking and calibration fees will be charged to the user. Systems and probes that remain in use after their end of life can be difficult to repair and maintain, so it is recommended to update the product after its end of life.

**Appendix A: Acoustic Output Report Table**  
**Acoustic Output Table**

System: PRE-ONE

Transducer Model: C3-A

Operation mode: B

<b>Index Label</b>			<b>MI</b>	<b>TIS</b>		<b>TIB</b>	<b>TIC</b>
				<b>Scan</b>	<b>Non-scan</b>		
					<b>Aaprt≤1c m<sup>2</sup></b>	<b>Aaprt &gt; 1cm<sup>2</sup></b>	<b>Non-scan</b>
<b>Global Maximum Index Value</b>			0.5	0.1			#
Associated Acoustic Parameter	p <sub>a</sub>	Mpa	0.92				
	P	mW		2			#
	min of [P <sub>a</sub> (Z <sub>a</sub> ), I <sub>a,a</sub> (Z <sub>a</sub> ) ]	mW					
	Z <sub>a</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	3.2				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	3.65	3.75			#
	Dim of A <sub>aprt</sub>	X	cm	2.09			#
		Y	cm	1.1			#
Other Information	t <sub>d</sub>	μs	0.57				
	prr	Hz	2293.6				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.23				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	35.21				
Operating Control Conditions	Mode		B	B			#
	Focus	cm	6	4			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: C3-A

Operation mode: THI-B

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	Non-scan
Associated Acoustic Parameter	Global Maximum Index Value		0.5	0.1			#
	p <sub>ta</sub>	Mpa	0.94				
	P	mW		2.01			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,u</sub> (Z <sub>s</sub> )]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	3.2				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	3.55	3.68			#
Other Information	Dim of A <sub>spet</sub>	X	cm		2.09		#
		Y	cm		1.1		#
	t <sub>d</sub>	μs	0.85				
	prr	Hz	2381				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	2.38				
Operating Control Conditions	d <sub>eq</sub> at max.I <sub>pi</sub>		cm				
	I <sub>pa,u</sub> at max.MI	W/cm <sup>2</sup>	35.32				
	Mode		THI-B	THI-B			#
Focus		cm	6	2			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: C3-A

Operation mode: THI-B+M

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Aaprt≤1cm <sup>2</sup>		Aaprt > 1cm <sup>2</sup>					
<b>Global Maximum Index Value</b>		0.4			0.2	0.3	#
Associated Acoustic Parameter	p <sub>a</sub>	Mpa	0.66				
	P	mW				23.55	#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,a</sub> (Z <sub>s</sub> )]	mW			10.27		
	Z <sub>s</sub>	cm			3.05		
	Z <sub>bp</sub>	cm			2.59		
	Z <sub>b</sub>	cm				3.54	
	Z at max.I <sub>pi,a</sub>	cm	2.91				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.82	
	f <sub>awf</sub>	MHz	3.48		3.5	3.45	#
	Dim of A <sub>apt</sub>	X	cm		6.96	6.96	#
		Y	cm		1.1	1.1	#
Other Information	t <sub>d</sub>	μs	0.55				
	prr	Hz	2293.6				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	0.87				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	15.02				
Operating Control Conditions	Mode		THI-B+M		THI-B+M	THI-B+M	#
	Focus	cm	5		11	6	#
	A Power	%	100		100	100	#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: C3-A

Operation mode: B+C

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Global Maximum Index Value		0.3			Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	0.64				#
Parameter	P	mW		20			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	3.6				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	3.85	4			#
	Dim of A <sub>aper</sub>	cm		2.09			#
	X	cm					#
Other Information	Y	cm		1.1			#
	t <sub>d</sub>	μs	1.26				
	prr	Hz	1824.8				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
Operating Control Conditions	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	42.13				
Mode		B+C	B+C				#
Focus	cm	5	3				#
A Power	%	100	100				#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: C3-A

Operation mode: PW

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan Aaprt≤1e m <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
<b>Global Maximum Index Value</b>		0.6				0.4	0.7
Associated Acoustic Parameter	p <sub>ra</sub>	Mpa	1				
	P	mW					36
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>1a,d</sub> (Z <sub>s</sub> ) ]	mW				22.03	
	Z <sub>s</sub>	cm				2.5	
	Z <sub>bp</sub>	cm				2.61	
	Z <sub>b</sub>	cm					4.95
	Z at max.I <sub>pi,a</sub>	cm	5				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.28	
	f <sub>awf</sub>	MHz	2.89			3.9	2.89
	Dim of A <sub>apt</sub>	X	cm			6.96	6.96
		Y	cm			1.1	1.1
Other Information	t <sub>d</sub>	μs	1.28				
	prr	Hz	4386				
	p <sub>f</sub> at max.I <sub>pi</sub>	MPa	1.6				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				0.28	
	I <sub>ps,a</sub> at max.MI	W/cm <sup>2</sup>	36.31				
Operating Control Conditions	Mode		PW			PW	PW
	Focus	cm	9			6	13
	A Power	%	100			100	100

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: V6-A

Operation mode: B

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
Global Maximum Index Value			0.4	0.1			#
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	0.91				
	P	mW		2			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	3.43				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	5.68	5.71			#
	Dim of A <sub>apt</sub>	X	cm	0.86			#
		Y	cm	0.7			#
Other Information	t <sub>d</sub>	μs	0.16				
	prr	Hz	3846.2				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.63				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	23.46				
Operating Control Conditions	Mode		B	B			#
	Focus	cm	1	0.5			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: V6-A

Operation mode: THI-B

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Global Maximum Index Value			0.6	0.3			#
Associated Acoustic Parameter	p <sub>ra</sub>	Mpa	1.44				
	P	mW		18			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	3.4				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	5.74	5.74			#
	Dim of A <sub>apt</sub>	X	cm	0.86			#
		Y	cm	0.7			#
Other Information	t <sub>d</sub>	μs	0.22				
	prr	Hz	4854				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	2.56				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	84.23				
Operating Control Conditions	Mode		THI-B	THI-B			#
	Focus	cm	3.5	3			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: V6-A

Operation mode: B+M

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>		
<b>Global Maximum Index Value</b>		0.8			0.1		0.1	
Associated Acoustic Parameter	p <sub>a</sub>	Mpa	1.89					
	P	mW			2		2	
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>a,a</sub> (Z <sub>s</sub> ) ]	mW						
	Z <sub>s</sub>	cm						
	Z <sub>bp</sub>	cm						
	Z <sub>b</sub>	cm				3.97		
	Z at max.I <sub>pi,a</sub>	cm	3.97					
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.07		
	f <sub>rawf</sub>	MHz	5.03		5.54		5.03	
Other Information	Dim of A <sub>input</sub>	X	cm		2.87		2.87	
		Y	cm		0.7		0.7	
	t <sub>d</sub>	μs	0.21					
	prr	Hz	3846.2					
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	3.73					
Operating Control Conditions	d <sub>eq</sub> at max.I <sub>pi</sub>		cm			0.07		
	I <sub>pa,a</sub> at max.MI		W/cm <sup>2</sup>	154.43				
	Mode		B+M		B+M		B+M	
	Focus	cm	1.5		0.5		1.5	
	A Power	%	100		100		100	

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: V6-A

Operation mode: THI-B+M

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Global Maximum Index Value			0.7	0.1		0.1	#
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	1.89				
	P	mW			2	2	#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>a,u</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>tp</sub>	cm					
	Z <sub>b</sub>	cm				3.97	
	Z at max.I <sub>pi,u</sub>	cm	3.95				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.07	
	f <sub>awf</sub>	MHz	5.05		5.48	5.05	#
	Dim of A <sub>apt</sub>	X	cm		2.87	2.87	#
		Y	cm		0.7	0.7	#
Other Information	t <sub>d</sub>	μs	0.2				
	prr	Hz	3846.2				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	3.73				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				0.07	
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	154.36				
Operating Control Conditions	Mode		THI-B+M		THI-B+M	THI-B+M	#
	Focus	cm	1.5		0.5	1.5	#
	A Power	%	100		100	100	#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: V6-A

Operation mode: B+C

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
Global Maximum Index Value			0.4	0.1			#
Associated Acoustic Parameter	p <sub>is</sub>	Mpa	1				
	P	mW		2			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>in,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	2.03				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	6.27	6.27			#
	Dim of A <sub>apt</sub>	cm		0.86			#
		Y	cm	0.7			#
Other Information	t <sub>d</sub>	μs	0.75				
	prr	Hz	3424.7				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.02				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pb,q</sub> at max.MI	W/cm <sup>2</sup>	13.43				
Operating Control Conditions	Mode		B+C	B+C			#
	Focus	cm	6.5	4.5			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: V6-A

Operating modeian: PW

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Global Maximum Index Value			0.3	0.1	0.1	#	
Associated Acoustic Parameter	p <sub>ia</sub>	Mpa	0.84				
	P	mW			2	2	#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ts,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm				3.3	
	Z at max.I <sub>pi,a</sub>	cm	3.47				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.23	
	f <sub>awf</sub>	MHz	6.3		6.3	6.3	#
	Dim of A <sub>apt</sub>	X	cm		2.87	2.87	#
		Y	cm		0.7	0.7	#
Other Information	t <sub>d</sub>	μs	0.78				
	prr	Hz	3424.7				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.84				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	27.45				
Operating Control Conditions	Mode		PW		PW	PW	#
	Focus	cm	1.5		1.5	1.5	#
	A Power	%	100		100	100	#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7M-A

Operation mode: B

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1c m <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
<b>Global Maximum Index Value</b>			0.3	0.1			#
Associated Acoustic Parameter	p <sub>a</sub>	Mpa	0.7				
	P	mW		16			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>pa,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	1.95				
	d <sub>cq</sub> (Z <sub>b</sub> )	cm					
	f <sub>swf</sub>	MHz	7.23	7.21			#
	Dim of A <sub>apt</sub>	cm		1.22			#
		Y		0.45			#
Other Information	t <sub>d</sub>	μs	0.2				
	ptr	Hz	3846.2				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.02				
	d <sub>cq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	32.96				
Operating Control Conditions	Mode		B	B			#
	Focus	cm	2	6			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7M-A

Operation mode: THI-B

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan Aaprt≤1e m <sup>2</sup>		
<b>Global Maximum Index Value</b>			0.7	0.1			#
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	0.69				
	P	mW		2			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>4a,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	1.35				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	6.85	6.85			#
	Dim of A <sub>apt</sub>	X	cm	1.22			#
		Y	cm	0.45			#
Other Information	t <sub>d</sub>	μs	0.23				
	prr	Hz	4082				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	2.34				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	105.36				
Operating Control Conditions	Mode		THI-B	THI-B			#
	Focus	cm	3	3			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7M-A

Operation mode: B+M

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	Non-scan
Associated Acoustic Parameter	Global Maximum Index Value		0.3		0.3		0.1
	p <sub>a</sub>	Mpa	0.83				#
	P	mW			10		10
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>tp</sub>	cm					
	Z <sub>b</sub>	cm				1.3	
	Z at max.I <sub>pi,a</sub>	cm	1.4				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				1.65	
	f <sub>awf</sub>	MHz	6.86		6.85		6.82
Other Information	Dim of	X	cm		4.08		4.08
	A <sub>apt</sub>	X	cm		0.45		0.45
		Y	cm				#
	t <sub>d</sub>	μs	0.2				
	prr	Hz	668.9				
Operating Control Conditions	p <sub>r</sub> at max.I <sub>pi</sub>		MPa	1.12			
	d <sub>eq</sub> at max.I <sub>pi</sub>		cm			1.65	
	I <sub>pa,e</sub> at max.MI		W/cm <sup>2</sup>	34.41			
	Mode		B+M		B+M		B+M
Focus		cm	4		7.5		3.5
A Power		%	100		100		100

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7M-A

Operation mode: THI-B+M

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan Aaprt≤1e m <sup>2</sup>		
<b>Global Maximum Index Value</b>		0.3		0.3		0.1	#
Associated Acoustic Parameter	p <sub>ta</sub>	Mpa	0.83				
	P	mW			10	10	#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm				1.3	
	Z at max.I <sub>pi,a</sub>	cm	1.4				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				1.65	
	f <sub>awf</sub>	MHz	6.84		6.83	6.82	#
	Dim of A <sub>apt</sub>	X	cm		4.08	4.08	#
		Y	cm		0.45	0.45	#
Other Information	t <sub>d</sub>	μs	0.2				
	prr	Hz	668.9				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.12				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				1.65	
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	34.38				
Operating Control Conditions	Mode		THI-B+M		THI-B+M	THI-B+M	#
	Focus	cm	4		7.5	3.5	#
	A Power	%	100		100	100	#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7M-A

Operation mode: B+C

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
Global Maximum Index Value			0.4	0.2			#
Associated Acoustic Parameter	p <sub>rh</sub>	Mpa	1.09				
	P	mW		16			#
	min of [P <sub>a</sub> (Z <sub>a</sub> ), I <sub>ta,a</sub> (Z <sub>a</sub> ) ]	mW					
	Z <sub>a</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	1.3				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	7.87	7.87			#
	Dim of A <sub>apt</sub>	X	cm	1.22			#
		Y	cm	0.45			#
Other Information	t <sub>d</sub>	μs	0.61				
	prr	Hz	6097				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.55				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,u</sub> at max.MI	W/cm <sup>2</sup>	37.77				
Operating Control Conditions	Mode		B+C	B+C			#
	Focus	cm	1	1			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7M-A

Operation mode: PW

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt ≤ 1c m <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
Global Maximum Index Value			0.8		0.9		0.8
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	1.98				
	P	mW			34		34
	min of [P <sub>u</sub> (Z <sub>s</sub> ), I <sub>ta,u</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>tp</sub>	cm					
	Z <sub>b</sub>	cm				1.5	
	Z at max.I <sub>pi,a</sub>	cm	3.35				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.27	
	f <sub>awf</sub>	MHz	6.87		6.83		6.83
	Dim of A <sub>apt</sub>	X	cm		4.08		4.08
		Y	cm		0.45		0.45
Other Information	t <sub>d</sub>	μs	0.59				
	prr	Hz	6970				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	3.17				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				0.27	
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	179.38				
Operating Control Conditions	Mode		PW		PW		PW
	Focus	cm	6.5		3.5		3.5
	A Power	%	100		100		100

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC3-A

Operation mode: B

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			
					Aaprt≤1c m <sup>2</sup>	Aaprt > 1cm <sup>2</sup>		
Global Maximum Index Value		0.4	0.1				#	
Associated Acoustic Parameter	p <sub>ra</sub>	Mpa	0.72					
	P	mW		4.32			#	
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,t</sub> (Z <sub>s</sub> ) ]	mW						
	Z <sub>s</sub>	cm						
	Z <sub>bp</sub>	cm						
	Z <sub>b</sub>	cm						
	Z at max.I <sub>pi,a</sub>	cm	3.35					
	d <sub>cq</sub> (Z <sub>b</sub> )	cm						
	f <sub>mf</sub>	MHz	3.2	3.54			#	
	Dim of A <sub>apt</sub>	X	cm	1.15			#	
		Y	cm	1.1			#	
Other Information	t <sub>d</sub>	μs	0.35					
	prr	Hz	2299					
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1					
	d <sub>cq</sub> at max.I <sub>pi</sub>	cm						
	I <sub>pa,q</sub> at max.MI	W/cm <sup>2</sup>	14.5					
Operating Control Conditions	Mode		B	B			#	
	Focus	cm	7	3			#	
	A Power	%	100	100			#	

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC3-A

Operation mode: THI-B

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Associated Acoustic Parameter	Global Maximum Index Value	0.4	0.1			#	
	p <sub>m</sub>	Mpa	0.69				
	P	mW		4.32			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>pa,u</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	3.35				
	d <sub>cq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	2.95	2.96			#
Other Information	Dim of X	cm		1.15			#
	A <sub>aprt</sub>	Y cm		1.1			#
	t <sub>a</sub>	μs	0.35				
	prr	Hz	2299				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.12				
Operating Control Conditions	d <sub>cq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,u</sub> at max.MI	W/cm <sup>2</sup>	12.02				
	Mode		THI-B	THI-B			#
Focus		cm	7	3			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC3-A

Operation mode: B+M

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Global Maximum Index Value			0.4		0.1	0.1	#
Associated Acoustic Parameter	p <sub>ta</sub>	Mpa	0.69				
	P	mW				2	#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,u</sub> (Z <sub>s</sub> ) ]	mW			1.29		
	Z <sub>s</sub>	cm			2		
	Z <sub>tp</sub>	cm			1.9		
	Z <sub>b</sub>	cm				3.45	
	Z at max.I <sub>pi,a</sub>	cm	3.45				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.58	
	f <sub>awf</sub>	MHz	2.95		2.95	2.95	#
	Dim of A <sub>apt</sub>	X	cm		3.84	3.84	#
		Y	cm		1.1	1.1	#
Other Information	t <sub>d</sub>	μs	0.33				
	prr	Hz	668.9				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.03				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				0.56	
	I <sub>pa,u</sub> at max.MI	W/cm <sup>2</sup>	14.7				
Operating Control Conditions	Mode		B+M		B+M	B+M	#
	Focus	cm	7		7	7	#
	A Power	%	100		100	100	#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC3-A

Operation mode: THI-B+M

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Global Maximum Index Value			0.3		0.1	0.1	#
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	0.51				
	P	mW				2	#
	min of [P <sub>u</sub> (Z <sub>s</sub> ), I <sub>ta,u</sub> (Z <sub>s</sub> ) ]	mW			1.29		
	Z <sub>s</sub>	cm			2		
	Z <sub>tp</sub>	cm			1.9		
	Z <sub>b</sub>	cm				3.45	
	Z at max.I <sub>pi,a</sub>	cm	3.42				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.58	
	f <sub>ref</sub>	MHz	2.89		2.91	2.92	#
	Dim of A <sub>apt</sub>	X	cm		3.84	3.84	#
		Y	cm		1.1	1.1	#
Other Information	t <sub>d</sub>	μs	0.32				
	prt	Hz	668.9				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.03				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				0.56	
	I <sub>pa,u</sub> at max.MI	W/cm <sup>2</sup>	14.63				
Operating Control Conditions	Mode		THI-B+M		THI-B+M	THI-B+M	#
	Focus	cm	7		7	7	#
	A Power	%	100		100	100	#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC3-A

Operation mode: B+C

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1e m <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
Global Maximum Index Value			0.6	0.1			#
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	1.03				
	P	mW		12			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ba,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	3.66				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>swf</sub>	MHz	2.95	2.95			#
Other Information	Dim of X	cm		1.15			#
	A <sub>apt</sub>	Y	cm	1.1			#
	t <sub>d</sub>	μs	0.24				
	prr	Hz	6097				
Operating Control Conditions	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.25				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	42.16				

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC3-A

Operation mode: PW

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Global Maximum Index Value			0.5	0.3		0.4	#
Associated Acoustic Parameter	p <sub>ta</sub>	Mpa	0.81				
	P	mW			10		10
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,u</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>tp</sub>	cm					
	Z <sub>b</sub>	cm				3.65	
	Z at max.I <sub>pi,a</sub>	cm	3.55				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.13	
	f <sub>awf</sub>	MHz	2.58		2.58		2.58
	Dim of A <sub>apt</sub>	cm		3.02		3.02	#
Other Information	X	cm					
	Y	cm		0.8		0.8	#
	t <sub>a</sub>	μs	0.65				
	prr	Hz	6098				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.41				
Operating Control Conditions	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				0.18	
	I <sub>pa,u</sub> at max.MI	W/cm <sup>2</sup>	23.63				
	Mode		PW		PW		PW
Focus	cm	3		3		3	#
A Power	%	100		100		100	#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: R7-A

Operation mode: B

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>		
<b>Global Maximum Index Value</b>			0.3	0.1			#	
Associated Acoustic Parameter	p <sub>ra</sub>	Mpa	0.81					
	P	mW		16			#	
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ba,a</sub> (Z <sub>s</sub> ) ]	mW						
	Z <sub>s</sub>	cm						
	Z <sub>bp</sub>	cm						
	Z <sub>b</sub>	cm						
	Z at max.I <sub>pi,a</sub>	cm	1.95					
	d <sub>eq</sub> (Z <sub>b</sub> )	cm						
	f <sub>awf</sub>	MHz	7.23	7.21			#	
	Dim of A <sub>apt</sub>	cm		1.22			#	
		Y		0.45			#	
Other Information	t <sub>d</sub>	μs	0.2					
	prr	Hz	3846.2					
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.02					
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm						
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	32.96					
Operating Control Conditions	Mode		B	B			#	
	Focus	cm	2	6			#	
	A Power	%	100	100			#	

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: R7-A

Operation mode: THI-B

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
Global Maximum Index Value			0.3	0.1			#
Associated Acoustic Parameter	P <sub>a</sub>	Mpa	0.79				
	P	mW		2			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,u</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	1.35				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	6.85	6.85			#
	Dim of A <sub>apt</sub>	cm		1.22			#
	X	cm					
	Y	cm		0.45			#
Other Information	t <sub>d</sub>	μs	0.23				
	prr	Hz	4082				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	2.34				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,u</sub> at max.MI	W/cm <sup>2</sup>	105.36				
Operating Control Conditions	Mode		THI-B	THI-B			#
	Focus	cm	3	3			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: R7-A

Operation mode: B+M

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
Global Maximum Index Value			0.3		0.3		0.1
Associated Acoustic Parameter	p <sub>ia</sub>	Mpa	0.83				
	P	mW			10		10
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					1.3
	Z at max.I <sub>pi,a</sub>	cm	1.4				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					1.65
	f <sub>awf</sub>	MHz	6.86		6.85		6.82
	Dim of A <sub>apt</sub>	X	cm		4.08		4.08
		Y	cm		0.45		0.45
Other Information	t <sub>d</sub>	μs	0.2				
	prr	Hz	668.9				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.12				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					1.65
	I <sub>pr,g</sub> at max.MI	W/cm <sup>2</sup>	34.41				
Operating Control Conditions	Mode		B+M		B+M		B+M
	Focus	cm	4		7.5		3.5
	A Power	%	100		100		100

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: R7-A

Operation mode: THI-B+M

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Global Maximum Index Value			0.3	0.3	0.1	#	
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	0.83				
	P	mW			10	10	#
	min of [P <sub>u</sub> (Z <sub>s</sub> ), I <sub>sa,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>tp</sub>	cm					
	Z <sub>b</sub>	cm				1.3	
	Z at max.I <sub>pi,a</sub>	cm	1.4				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				1.65	
	f <sub>awf</sub>	MHz	6.72		6.81	6.79	#
	Dim of A <sub>apt</sub>	X	cm		4.08	4.08	#
		Y	cm		0.45	0.45	#
Other Information	t <sub>d</sub>	μs	0.2				
	prr	Hz	668.9				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.12				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				1.65	
	I <sub>ps,a</sub> at max.MI	W/cm <sup>2</sup>	34.22				
Operating Control Conditions	Mode		THI-B+M		TIII-B+M	THI-B+M	#
	Focus	cm	4		7.5	3.5	#
	A Power	%	100		100	100	#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: R7-A

Operation mode: B+C

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
<b>Global Maximum Index Value</b>			0.4	0.2			#
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	1.09				
	P	mW		16			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,u</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	1.3				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	7.87	7.87			#
	Dim of A <sub>apt</sub>	X	cm	1.22			#
		Y	cm	0.45			#
Other Information	t <sub>d</sub>	μs	0.61				
	prr	Hz	6097				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.55				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,u</sub> at max.MI	W/cm <sup>2</sup>	37.77				
Operating Control Conditions	Mode		B+C	B+C			#
	Focus	cm	1	1			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: R7-A

Operation mode: PW

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan Aaprt≤1cm <sup>2</sup>		
<b>Global Maximum Index Value</b>		0.8			0.9		0.8
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	1.98				
	P	mW			34		34
	min of [P <sub>u</sub> (Z <sub>s</sub> ), I <sub>ta,u</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>ep</sub>	cm					
	Z <sub>b</sub>	cm				1.5	
	Z at max.I <sub>pi,a</sub>	cm	3.35				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.27	
	f <sub>swf</sub>	MHz	6.87		6.83		6.83
	Dim of A <sub>apt</sub>	X	cm		4.08		4.08
		Y	cm		0.45		0.45
Other Information	t <sub>d</sub>	μs	0.59				
	prr	Hz	6970				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	3.17				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				0.27	
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	179.38				
Operating Control Conditions	Mode		PW		PW		PW
	Focus	cm	6.5		3.5		3.5
	A Power	%	100		100		100

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC6-A

Operation mode: B

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>		
<b>Global Maximum Index Value</b>			0.8	0.1			#	
Associated Acoustic Parameter	p <sub>a</sub>	Mpa	1.94					
	P	mW		18			#	
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>in,a</sub> (Z <sub>s</sub> ) ]	mW						
	Z <sub>s</sub>	cm						
	Z <sub>bp</sub>	cm						
	Z <sub>b</sub>	cm						
	Z at max.I <sub>pi,a</sub>	cm	3.2					
	d <sub>eq</sub> (Z <sub>b</sub> )	cm						
	f <sub>mf</sub>	MHz	5.86	5.89			#	
	Dim of A <sub>apt</sub>	X	cm	0.73			#	
		Y	cm	0.7			#	
Other Information	t <sub>d</sub>	μs	0.25					
	prr	Hz	4854					
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	3.11					
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm						
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	90.12					
Operating Control Conditions	Mode		B	B			#	
	Focus	cm	3	6.5			#	
	A Power	%	100	100			#	

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC6-A

Operation mode: THI-B

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Global Maximum Index Value			0.6	0.1			#
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	1.49				
	P	mW		20			#
	min of [P <sub>u</sub> (Z <sub>s</sub> ), I <sub>ba,u</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	3.3				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>swf</sub>	MHz	5.68	5.67			#
	Dim of A <sub>apt</sub>	X	cm	1.22			#
		Y	cm	0.7			#
Other Information	t <sub>d</sub>	μs	0.29				
	prr	Hz	4854				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	3.01				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,u</sub> at max.MI	W/cm <sup>2</sup>	90.26				
Operating Control Conditions	Mode		B	B			#
	Focus	cm	3	4			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC6-A

Operation mode: B+M

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1e m <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
<b>Global Maximum Index Value</b>			0.3		0.4		0.1
Associated Acoustic Parameter	p <sub>ts</sub>	Mpa	0.61				#
	P	mW			16		16
	min of [P <sub>u</sub> (Z <sub>s</sub> ), I <sub>ts,a</sub> (Z <sub>s</sub> )]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>tp</sub>	cm					
	Z <sub>b</sub>	cm					1.95
	Z at max.I <sub>pi,a</sub>	cm	2.05				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					3.39
	f <sub>awf</sub>	MHz	5.56		5.46		5.46
	Dim of A <sub>aprt</sub>	X	cm		2.43		2.43
		Y	cm		0.7		0.7
Other Information	t <sub>d</sub>	μs	0.25				
	prr	Hz	400				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	0.75				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					3.27
	I <sub>pu,u</sub> at max.MI	W/cm <sup>2</sup>	12.25				
Operating Control Conditions	Mode		B+M		B+M		B+M
	Focus	cm	3		5		5
	A Power	%	100		100		100

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC6-A

Operation mode: THI-B+M

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Global Maximum Index Value			0.3	0.4		0.1	#
Associated Acoustic Parameter	p <sub>ra</sub>	Mpa	0.61				
	P	mW			16	16	#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>a,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm				1.95	
	Z at max.I <sub>pi,a</sub>	cm	2.05				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				3.39	
	f <sub>awf</sub>	MHz	5.52		5.43	5.45	#
	Dim of A <sub>apt</sub>	cm			2.43	2.43	#
		Y	cm		0.7	0.7	#
Other Information	t <sub>d</sub>	μs	0.25				
	prr	Hz	400				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	0.75				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				3.27	
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	12.21				
Operating Control Conditions	Mode		THI-B+M		THI-B+M	THI-B+M	#
	Focus	cm	3		5	5	#
	A Power	%	100		100	100	#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC6-A

Operation mode: B+C

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan Aaprt≤1c m <sup>2</sup>		
<b>Global Maximum Index Value</b>			0.5	0.5			#
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	1.11				
	P	mW		46			#
	min of [P <sub>u</sub> (Z <sub>s</sub> ), I <sub>ta,0</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	2.55				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	5.89	5.89			#
	Dim of A <sub>apt</sub>	X	cm	0.73			#
		Y	cm	0.7			#
Other Information	t <sub>d</sub>	μs	0.99				
	prr	Hz	6097				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.45				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pe,u</sub> at max.MI	W/cm <sup>2</sup>	32.65				
Operating Control Conditions	Mode		B+C	B+C			#
	Focus	cm	4	4			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: MC6-A

Operation mode: PW

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
Global Maximum Index Value			0.2		0.9		0.8
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	0.49				
	P	mW			82		82
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>tp</sub>	cm					
	Z <sub>b</sub>	cm				2.3	
	Z at max.I <sub>pi,a</sub>	cm	0.01				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				1.24	
	f <sub>swf</sub>	MHz	5.23		5.23		5.23
	Dim of A <sub>apt</sub>	X	cm		2.43		2.43
		Y	cm		0.7		0.7
Other Information	t <sub>d</sub>	μs	1.02				
	prr	Hz	4000				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	0.57				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				0.57	
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	8.52				
Operating Control Conditions	Mode		PW		PW		PW
	Focus	cm	5		5		5
	A Power	%	100		100		100

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7S-A

Operation mode: B

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Aaprt $\leq 1\text{cm}^2$		Aaprt $> 1\text{cm}^2$	Non-scan				
Global Maximum Index Value		0.7	0.1				#
Associated Acoustic Parameter	p <sub>a</sub>	Mpa	1.92				
	P	mW		2			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,u</sub>	cm	1.5				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>mf</sub>	MHz	7.72	8.16			#
Other Information	Dim of A <sub>apt</sub>	X	cm	0.77			#
		Y	cm	0.5			#
	t <sub>d</sub>	μs	0.15				
	prr	Hz	3831				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	1.52				
Operating Control Conditions	d <sub>eq</sub> at max.I <sub>pi</sub>		cm				
	I <sub>pa,g</sub> at max.MI		W/cm <sup>2</sup>	61.29			
	Mode		B	B			#
	Focus	cm	3	7.5			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7S-A

Operation mode: THI-B

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
Global Maximum Index Value			0.4	0.1			#
Associated Acoustic Parameter	P <sub>a</sub>	Mpa	0.99				
	P	mW		12			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>b0</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pl,a</sub>	cm	1.52				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	6.15	6.42			#
	Dim of A <sub>apt</sub>	X	cm	0.77			#
		Y	cm	0.5			#
Other Information	t <sub>d</sub>	μs	0.21				
	prr	Hz	3831				
	p <sub>r</sub> at max.I <sub>pl</sub>	MPa	1.14				
	d <sub>eq</sub> at max.I <sub>pl</sub>	cm					
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	45.26				
Operating Control Conditions	Mode		THI-B	THI-B			#
	Focus	cm	3	7.5			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7S-A

Operation mode: B+M

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			
					Aaprt≤1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>		
<b>Global Maximum Index Value</b>			0.8		0.1		0.2	
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	1.92				#	
	P	mW			2		2	
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>da,a</sub> (Z <sub>s</sub> ) ]	mW						
	Z <sub>s</sub>	cm						
	Z <sub>bp</sub>	cm						
	Z <sub>b</sub>	cm				1.55		
	Z at max.I <sub>pi,u</sub>	cm	1.5					
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.08		
	f <sub>awf</sub>	MHz	6.66		8.01		6.66	
Other Information	Dim of X	cm			2.56		2.56	
	A <sub>aprt</sub>	Y cm			0.5		0.5	
	t <sub>d</sub>	μs	0.17					
	prr	Hz	4717					
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	2.72					
Operating Control Conditions	d <sub>eq</sub> at max.I <sub>pi</sub>	cm						
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	215.57					
	Mode		B+M		B+M		B+M	
Focus		cm	6.5		0.5		6.5	
	A Power	%	100		100		100	

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7S-A

Operation mode: THI-B+M

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			
					Aaprt≤1e m <sup>2</sup>	Aaprt > 1cm <sup>2</sup>		
<b>Global Maximum Index Value</b>		0.7			0.1		0.2	
Associated Acoustic Parameter	p <sub>a</sub>	Mpa	1.81					
	P	mW			2		2	
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ba,a</sub> (Z <sub>s</sub> ) ]	mW						
	Z <sub>s</sub>	cm						
	Z <sub>bp</sub>	cm						
	Z <sub>b</sub>	cm				1.55		
	Z at max.I <sub>pi,a</sub>	cm	1.5					
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.08		
	f <sub>awf</sub>	MHz	6.63		7.92		6.68	
	Dim of A <sub>aprt</sub>	X	cm		2.56		2.56	
		Y	cm		0.5		0.5	
Other Information	t <sub>d</sub>	μs	0.17					
	prr	Hz	4717					
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	2.71					
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				0.07		
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	215.32					
Operating Control Conditions	Mode		THI-B+M		THI-B+M		THI-B+M	
	Focus	cm	6.5		0.5		6.5	
	A Power	%	100		100		100	

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7S-A

Operation mode: B+C

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
Global Maximum Index Value			0.7	0.1			#
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	2.06				
	P	mW		32			#
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ts,a</sub> (Z <sub>s</sub> )]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm					
	Z at max.I <sub>pi,a</sub>	cm	1.5				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm					
	f <sub>awf</sub>	MHz	7.99	8.28			#
	Dim of A <sub>apt</sub>	X	cm	0.77			#
		Y	cm	0.5			#
Other Information	t <sub>d</sub>	μs	0.62				
	prr	Hz	3424.7				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	3.12				
	d <sub>eq</sub> at max.I <sub>pi</sub>	cm					
	I <sub>pa,a</sub> at max.MI	W/cm <sup>2</sup>	184.6				
Operating Control Conditions	Mode		B+C	B+C			#
	Focus	cm	5.5	2.5			#
	A Power	%	100	100			#

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

**Acoustic Output Table**

System: PRE-ONE

Transducer Model: L7S-A

Operation mode: PW

Index Label			MI	TIS		TIB	TIC
				Scan	Non-scan		
					Aaprt ≤ 1cm <sup>2</sup>	Aaprt > 1cm <sup>2</sup>	
Global Maximum Index Value			0.8		1.2		1.7
Associated Acoustic Parameter	p <sub>m</sub>	Mpa	2.26				
	P	mW			30		30
	min of [P <sub>a</sub> (Z <sub>s</sub> ), I <sub>ta,a</sub> (Z <sub>s</sub> ) ]	mW					
	Z <sub>s</sub>	cm					
	Z <sub>bp</sub>	cm					
	Z <sub>b</sub>	cm				1.5	
	Z at max.I <sub>pi,a</sub>	cm	1.5				
	d <sub>eq</sub> (Z <sub>b</sub> )	cm				0.18	
	f <sub>swf</sub>	MHz	7.95		8.15		7.97
Other Information	Dim of X	cm			2.56		2.56
	A <sub>apt</sub>	Y	cm		0.5		0.5
	t <sub>d</sub>	μs	0.62				
	prr	Hz	3424.7				
	p <sub>r</sub> at max.I <sub>pi</sub>	MPa	3.05				
Operating Control Conditions	d <sub>eq</sub> at max.I <sub>pi</sub>	cm				2.68	
	I <sub>pa,u</sub> at max.MI	W/cm <sup>2</sup>	141.73				
	Mode		PW		PW		PW
Focus		cm	5.5		2.5		4.5
	A Power	%	100		100		100

NOTE1: Data can only be entered in one column related to TIS.

NOTE2: Information is not required to be provided regarding the TIC for any ASSEMBLY TRANSDUSER that is not intended for transcranial or neonatal head scanning.

NOTE3: If the requirements of 201.12.4.2a) are met, there is no need to enter any data into the fields related to TIS, TIB, or TIC.

NOTE4: If the requirements of 201.12.4.2b) are met, there is no need to enter any data into the MI-related fields.

## Appendix B: Manufacturer's Instructions and Declarations

1. Manufacturer's Instructions and Declarations – Electromagnetic Emissions		
The PRA-ONE is intended for use in the electromagnetic environment specified below. The customer or the user of the PRA-ONE must ensure that the device is used in the environment described below.		
Emission Test	Suitability	Electromagnetic environmental instructions
RF Emissions CISPR II	Group 1	The PRA-ONE uses RF energy only for internal functions. Therefore, the RF emission is very low and does not cause interference to nearby electronic devices.
RF Emissions CISPR II	Class A	PRA-ONE is suitable for use in any building, including domestic buildings and buildings that are directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emission IEC 61000-3-2	Class A	
Voltage fluctuation Flickering Emission IEC 61000-3-3	In accordance	

2. Manufacturer's Instructions and Declarations – Electromagnetic Immunity			
The PRA-ONE is intended for use in specific electromagnetic environments. The user must ensure that the device is used in the environment described below.			
Immunity Test	IEC 60601	Conformity level	Electromagnetic environmental instructions
Electrostatic discharge (ESD) IEC 61000-4-2	Contact ±6 kV Air ±8 kV	Contact ±6 kV Air ±8 kV	Floors must be wood, concrete, or ceramic. If the floor is covered with synthetic material, the relative humidity is as low as 30%
Electric/explosive fast transient IEC 61000-4-4	±2 kV for mains line ±1 kV for line input/output	±2 kV for mains line ±1 kV for line input/output	The quality of the main power source must be of a commercial type or hospital environment
spike IEC 61000-4-5	±1 kV line to line ±1 kV line to earth	±1 kV line to line ±1 kV line to earth	
Interrupts and voltage variations on the mains input line IEC 61000-4-11	<5% UT (>95% submerged in UT) for 0.5 . cycle 40% UT (60% submerged in UT) for 5 . cycle 70% UT (30% submerged in UT) for 25 . cycle <5% UT (>95% submerged in UT) for 5 seconds	<5% UT (>95% submerged in UT) for 0.5 . cycle 40% UT (60% submerged in UT) for 5 . cycle 70% UT (30% submerged in UT) for 25 . cycle <5% UT (>95% submerged in UT) for 5 seconds	The quality of the main power source must be of a commercial type or hospital environment. If the PRA-ONE user requires continuous operation during a power supply interruption, it is recommended to supply the PRA-ONE via an

			uninterrupted mains source (UPS) or battery.
Magnetic field power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	The magnetic field power frequency must be at the level characteristic of a typical commercial location or hospital environment.
NOTE: UT is the main AC voltage before application at the test level.			

3. User instructions and declarations – electromagnetic immunity			
The PRA-ONE is intended for use in specific electromagnetic environments. The user must ensure that the device is used in the environment described below.			
Immunity Test	IEC 60601 test level	IEC 60601 test level	Electromagnetic environmental instructions
RF Conduction IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment must be used remotely from the PRA-ONE, including cables, with the recommended distance measured from the equation used in the transmit frequency. Recommended separation distance $d = 1.2 \sqrt{P}  $ $d = 1.2 \sqrt{P}  $ 80MHz to 800MHz $d = 2.3 \sqrt{P}  $ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) The field strength of the fixed RF transmitter, as determined by the electromagnetic survey area must be less than the appropriate level in each frequency range. Interference may occur in devices marked with symbols such as these: 
<p>NOTE1: At 80 MHz and 800 MHz, a higher frequency is used.</p> <p>NOTE2: These instructions may not work in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> <p>Field strengths from fixed transmitters, such as base stations for radio (cellular/wireless), telephone, and mobile radio, amateur radio, AM and FM, radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the PRA-ONE is used exceeds the applicable RF compatibility level, the PRA-ONE must be observed to verify normal operation. If performance is</p>			

abnormal, additional measurements may be required, such as a reorientation adjustment or PRA-ONE relocation. The frequency range is above 150 kHz to 80 MHz, the field strength must be less than 3 V/m.

Recommended separation distance between a portable or mobile RF communication device and the PRA-ONE			
Maximum output power of transmitter (W)	Separation distance based on transmitter frequency (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum output power not listed above, it is recommended that the separation distance d in meters (m) be estimated using the equation applicable to the transmitter frequency, where P is the transmitter's maximum output power rating in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, distance separation for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

**Appendix C: Summary of Measurement Results**

Measurement	Useful Range	Accuracy
Distance	Full Screen/ Full screen	< ± 5%
Circumference / circumference: Trace method, ellipse method	Full Screen/ Full screen	< ± 5%
Large: Trace method, ellipse method	Full Screen/ Full screen	< ± 10%
Volume	Full Screen/ Full screen	< ± 10%
Corner	Full Screen/ Full screen	< ± 5%
Time	Full Screen/ Full screen	< ± 5%
Heart rate	Full Screen/ Full screen	< ± 5%
Speed/speed	Full Screen/ Full screen	< ± 10%

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**Appendix D: Display Accuracy and Uncertainty of Acoustic Measurement**

According to IEC60601-2-37 and NEMA UD-3 of 2004, the display accuracy and uncertainty of acoustic measurements are summarized in the table below.

The display accuracy of MI is  $\pm 20\%$ , and TI is  $\pm 40\%$  or  $<0.1$ , if MI, TI is below 0.5.

Items	Measurement uncertainty (Percentage, 95% Confidence Value)
Center Frequency	$\pm 15\%$
Acoustic Power	$\pm 30\%$
Acoustic Intensity	$\pm 30\%$
Peak Refractional Pressure	$\pm 15\%$

**Appendix E: Transducer Surface Maximum Temperature**

According to the requirements of section 42.3 of IEC standard 60601-2-37:2007, the surface temperature of the transducer has been tested under two kinds of conditions: the transducer is suspended in fixed air or the transducer is attached to a material similar to human tissue. Calculation of uncertainty is based on ISO Guide tout ye Expression of Uncertainty in Measurement. Three transducer samples were tested and the confidence coefficient was 95%, the t.975 value was 4.30.

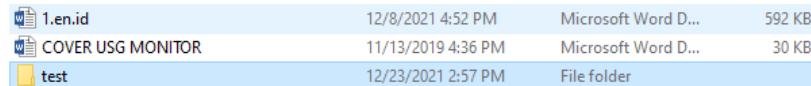
The measurement data were obtained under the test conditions used at PT. Sinko Prima Alloy.

Transducer Model	Surface Maximum Temperature
C3-A	< 41.0
MC-A	< 41.0
L7M-A	< 41.0
R7-A	< 41.0
L7S-A	< 41.0
MC3-A	< 41.0
V6-A	< 41.0

## Appendix F: PRA-ONE Network Sharing Setup Procedure

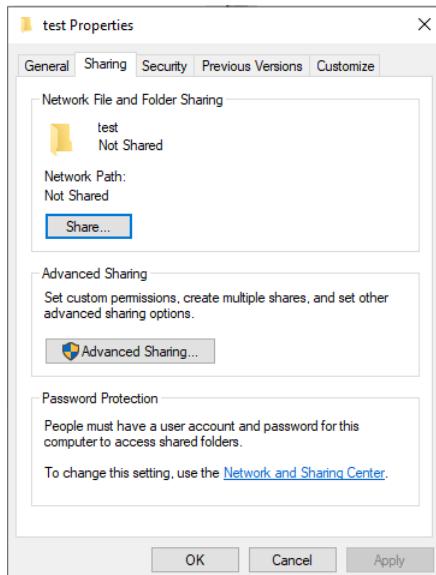
### Settings in Windows, set document sharing

1. Select the document you want to share, name the document "test"

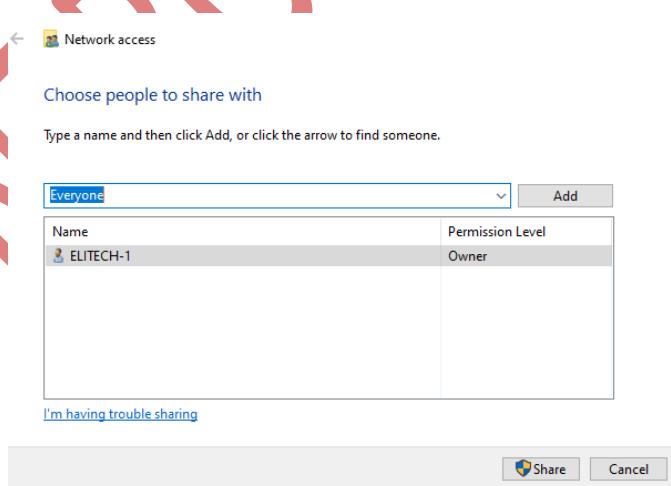


1.en.id	12/8/2021 4:52 PM	Microsoft Word D...	592 KB
COVER USG MONITOR	11/13/2019 4:36 PM	Microsoft Word D...	30 KB
test	12/23/2021 2:57 PM	File folder	

2. Right click on the document, select "properties" and click "share"



3. You can see the sharing settings interface, as you can see in the picture, select “everyone”, then click “add”



4. Select “read/write” at the permission level on everyone, click “share”, then confirm

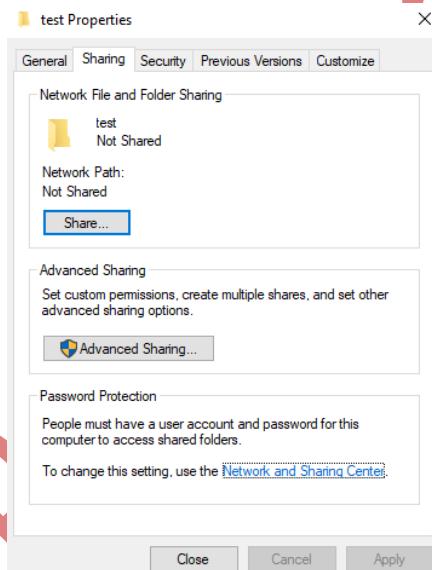
Choose people to share with  
Type a name and then click Add, or click the arrow to find someone.

Name	Permission Level
ELITECH-1	Owner
Everyone	Read/Write ▾

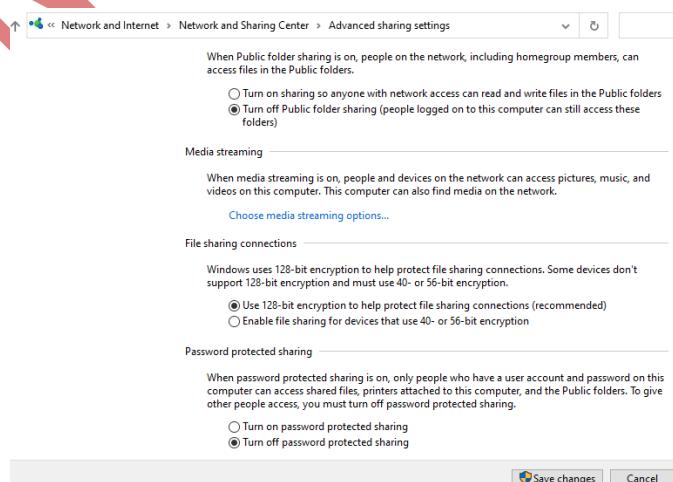
I'm having trouble sharing

Share Cancel

5. If windows has not set the code, then turn off password protection. Instructions can be seen in the following image  
a.) Click "network and sharing center" in the sharing properties.



- b.) In the network interface and sharing center, select “public”, in the share with password protection, turn off password protection.



## Settings in PRE-ONE

### IP Settings

- First, confirm the file sharing service address, you can get the IP address in the windows interface. On windows "start" - "run" type "cmd" and press enter, then type "ipconfig" and press enter, you can see IP address of local service.

```
Connection-specific DNS Suffix . .
Link-local IPv6 Address . . . . . : fe80::d81e:e058:f895:396d%23
IPv4 Address . . . . . : 192.168.1.131
Subnet Mask . . . . . : 255.255.255.0
Default Gateway . . . . . : 192.168.1.1
```

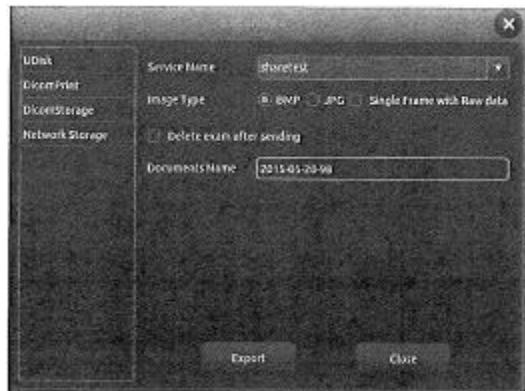
- Enter into the PRA-ONE setup interface, select net. Select "DHCP" (automatically obtain IP address) or "static" (type IP address manually);

**⚠️ TIP:** if you want to type the IP address manually, make sure that the IP address is on the part of the internet that corresponds to the service, otherwise it will be confused with the IP in the LAN.



- Select the "storage" net interface, type the service name, IP address, username, password, and the name of the shared file, click "add" to add a storage network, you can choose the export route as shown in the following image.





**⚠️ WARNING:**

**Ping:** check whether the IP is connected or not

**clear:** removes all IP addresses, usernames, passwords, and names from shared files

**Updates:** update content to select items

**Delete:** delete the selected service item

**Defaults:** set selected item as default net route

**⚠️ NOTE:** You can add members of the network storage service to make transmissions between multiple systems.

**⚠️ NOTE:** If windows turn off password protection, then PRA-ONE is finished setting up, you can type username and password at any time.



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